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ROYAL COMMISSION OF INQUIRY INTO CERTAIN
DEATHS AT THE HOSPITAL FOR SICK CHILDREN AND
RELATED MATTERS.

Hearing held in Court Room 20
Court House
361 University Avenue
Toronto, Ontario

The Honourable Mr. Justice **S.G.M. Grange**

Commissioner

P.S.A. Lamek, Q.C.

Counsel

E.A. Cronk

Associate Counsel

Thomas Millar

Administrator

Transcript of evidence
for

July 5th, 1983

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Tuesday the 5th day of July,
1983.

- - - -

THE HONOURABLE MR. JUSTICE S.G.M. GRANGE - Commissioner
THOMAS MILLAR - Administrator
MURRAY R. ELLIOT - Registrar

- - - -

APPEARANCES:

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D. HUNT)	Counsel for the Attorney-
L. CECCHETTO)	General and Solicitor
	General of Ontario (Crown
	Attorneys and Coroner's Office)
I.G. SCOTT, Q.C.)	Counsel for The Hospital for
I.J. ROLAND)	Sick Children
R. DEVINS)	
B. PERCIVAL, Q.C.)	Counsel for The Metropolitan
D. YOUNG)	Toronto Police
W.N. ORTVED)	Counsel for numerous Doctors
K. CHOWN)	at The Hospital for Sick
	Children
B. SYMES)	Counsel for the Registered
F. KITELY)	Nurses' Association of Ontario
	and 35 Registered Nurses at
	The Hospital for Sick Children

(Cont'd)



APPEARANCES: (Continued)

H. SOLOMON	Counsel for the Ontario Association of Registered Nursing Assistants
W.A. BOGART	Counsel for Susan Nelles - Nurse
G.R. STRATHY) P. RAE)	Counsel for Phyllis Trayner - Nurse
C. BUHR	Counsel for Sui Scott - Nurse
N. GOODMAN	Counsel for Mrs. M. Christie - R.N.A.
J.A. OLAH	Counsel for Janet Brownless (Vereecken) - R.N.A.
M. MANNING, Q.C.) S. LABOW)	Counsel for Mr. & Mrs. Gosselin, Mr. & Mrs. Gionas, Mr. & Mrs. Inwood, Mr. & Mrs. Turner, and Mr. & Mrs. Lutes (parents of deceased children)
F.J. SHANAHAN	Counsel for Mr. & Mrs. Dominic Lombardo (parents of deceased child Stephanie Lombardo)
W.W. TOBIAS	Counsel for Mr. & Mrs. Hines, (parents of deceased child Jordan Hines)

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---Upon commencing at 10:00 a.m.

THE COMMISSIONER: Mr. Lamek, have
you anything? Ms. Cronk?

MR. LAMEK: No thanks, Mr. Commissioner.

MS. CRONK: Mr. Commissioner, with
your concurrence, I propose to start this morning by
dealing with the Statement of Prima Facie Facts.
You will recall that on Thursday last Commission
Counsel indicated that in light of the written
comments and/or objections that had been received
from various counsel an addendum to the Statement
of Prima Facie Facts have been prepared by Commission
Counsel and I propose briefly to deal with that at
the time, sir.

THE COMMISSIONER: All right.

MS. CRONK: You will recall,
Mr. Commissioner, that on Tuesday, June 21st,
Mr. Lamek tendered as an exhibit before you the
Statement of Prima Facie Facts prepared by Commission
staff. At that time you received a number of
submissions from various counsel concerning the
contents of the Statement and concerning the timing
and format of its release.

As a result of those submissions, all
counsel were invited to make their objections

1
2 regarding the Statement and its contents known to
3 Commission Counsel and, similarly, were invited
4 to provide Commission Counsel with their suggested
5 amendments, if any, by Monday, June 27th.

6 Some counsel of course you will recall,
7 Mr. Commissioner, had as at June 21st, already
8 provided written comments to Commission Counsel with
9 respect to the Statement of Prima Facie Facts and,
10 indeed, Mr. Scott on behalf of the Hospital, filed
11 before you on that day his comments with respect
12 to the Statement and those comments were filed as
Exhibit 3A before you.

13 In light of the submissions made to
14 you, Mr. Commissioner, by various counsel and the
15 comments received during the last week from various
16 other counsel concerning the Statement, there are
17 a number of very brief comments by way of response
18 or commentary which Commission Counsel wish to make
concerning the statement.

19 First, regarding the question of onus.
20 You will recall, Mr. Commissioner, that Mr. Marshall,
21 Mr. Sopinka and a number of other counsel raised
22 issue before you on June 21st as to the nature of
23 the onus which should apply in respect of those facts
24 set out in the Statement. You indicated in that
25



1
2 regard, Mr. Commissioner, that where any counsel
3 objected to a particular fact in the Statement,
4 whether on the ground of alleged inaccuracy or lack
5 of completeness and where that fact was material or
6 relevant in your view to the matters before you at
7 this Commission, in the normal course Commission
8 Counsel should lead evidence in respect of that
9 fact or facts.

10 You further indicated that where the
11 fact in issue in your view had either very little
12 relevance or if you thought it had been adequately
13 proved, you would approach the matter with some
14 flexibility and might well require other counsel
15 to satisfy you that the issue or fact should be
16 further explored in evidence.

17 Commission Counsel wish to make it
18 clear at this stage, Mr. Commissioner, that it was
19 always the intent to lead evidence before you
20 concerning many of the facts set out in the Statement.
21 It was and is our hope however in respect of less
22 material or less relevant facts that viva voce
23 evidence need not be called.

24 The second submission you will recall
25 Mr. Commissioner, that was raised before you on
June 21st was one made by Mr. Marshall in his



1
2 submissions when he drew your attention to the
3 contents of paragraph 6 on page 9 of the Statement
4 where it is stated, and I quote:

5 "Although the information contained in
6 the Dubin Report was current as at
7 January, 1983, the time period relevant
8 to this Commission is July, 1980 to
9 March, 1981."

10 That's found, Mr. Commissioner, on
11 page 9 of the Statement, paragraph 6.

12 Lest there be any confusion,
13 Mr. Commissioner, as to the time period considered
14 by Commission Counsel to be relevant to your terms
15 of reference, we wish to point out that the statement
16 made in paragraph 6 was made expressly in the
17 context of the contents in the Dubin Report. It was
18 done in that context because the Dubin Report, as
19 you are aware, sir, was published and released to
20 the public in January of 1983. Many of the facts
21 contained in the Dubin Report, therefore, are, on
22 the basis of the public record as it now stands,
23 accurate as at January, 1983, but may not be an
24 accurate reflection of the situation in the Hospital
25 during the period July, 1980 to March, 1981.

There are however, sir, many matters



1
2 of relevance or matters which Commission Counsel
3 would submit are of relevance to you which date
4 from after March, 1981; as, for example, to name
5 but a few, the Preliminary Hearing concerning Susan
6 Nelles which commenced in January of 1982, the
7 Police investigation conducted with respect to
8 these deaths which continued after the discharge
9 of Susan Nelles in May of 1982 and finally, amongst
10 other matters, many of the digoxin test results
11 obtained with respect to the relevant children
12 including final autopsy reports in some cases,
13 which were not obtained until well after March, 1981.

14 The relevance, therefore, of the time
15 period July, 1980 to March, 1981 is that the deaths
16 with which we are concerned arose during this period
17 with the exception of one child who died on June
18 30th, 1983, that is, one day before commencement of
19 the Inquiry period.

20 It should not be taken, in my
21 submission, therefore, Mr. Commissioner, from
22 paragraph 6 of the Statement of Prima Facie Facts
23 or, indeed, from any of the other contents of the
24 Statement that only those events occurring during
25 July, 1980 to March, 1981 are concerned by Commission
Counsel to be relevant to this Commission's hearings.



1
2 The third area of submissions which
3 I wish to address this morning, Mr. Commissioner,
4 relates to the medical case summaries which are
5 contained in the Statement of Facts.

6 You will recall in this regard, sir,
7 that Mr. Scott raised this matter with you on June
8 21st and questioned the advisability of including
9 in the Statement of Prima Facie Facts medical case
10 summaries of the relevant children which, according
11 to Mr. Scott at that time, his clients felt in many
cases to be either inaccurate or incomplete.

12 He expressed concern before you as
13 well as to the authorship of some of these summaries
14 and suggested that in some cases they appear to have
15 been prepared by unnamed persons.

16 It is made very clear in the Statement
17 of Prima Facie Facts on a full reading of its text,
18 Mr. Commissioner, that the medical case summaries
19 were drawn from one or more of only three sources;
20 the first being Appendix 2 to the Atlanta Report,
21 that is, from summaries prepared by the authors of
that report or their consultants.

22 The second source being case summaries
23 prepared by Dr. Alois Hastreiter for the
24 Metropolitan Toronto Police investigative team.
25



1
2 Dr. Hastreiter will be called as a witness at forth-
3 coming hearings before you, sir.

4 Finally, the third source was from
5 the Hospital medical charts and records themselves.
6 No other source was used by Commission staff in
7 including in the Statement these medical case
8 summaries.

9 It should be pointed out as well,
10 sir, that the only information drawn directly from
11 the Hospital medical charts and records as distinct
12 from the medical case summaries contained in Appendix
13 2 to the Atlanta Report and as distinct from
14 Dr. Hastreiter's summaries relate to one of two
15 things: first, the final autopsy findings on a
16 particular child wherein an autopsy was conducted,
17 or the name of the hospital for which the child
18 had been transferred to The Hospital for Sick
19 Children. Those were the matters drawn directly
20 from the medical charts and records for the purposes
21 of consistency between the case summaries drawn from
22 Appendix 2 to the Atlanta Report and the case
23 summaries prepared by Dr. Hastreiter.

24 It was also made, in my submission,
25 Mr. Commissioner, expressly clear in the Statement
of Prima Facie facts that there are in many, many



1
2 instances discrepancies between the facts contained,
3 and by that I mean the facts contained in the
4 medical case summaries, in Appendix 2 to the
5 Atlanta Report as compared to the case summaries
6 and the facts in those summaries prepared by
7 Dr. Hastreiter. Indeed, there are many discrepancies,
8 as is pointed out in the Statement of Prima Facie
9 Facts between the medical case summary facts set
10 out in those two sources and the facts set out in
the hospital records and charts themselves.

11 Commission Counsel, in the text of
12 the Statement of Prima Facie Facts acknowledged these
13 discrepancies and further expressly undertook, and
14 I repeat that undertaking today, to call evidence
15 at forthcoming hearings to clarify these discrepancies
16 and to establish the basis upon which this Commission
17 will be looking at the children named in the Statement
of Prima Facie facts, that is, 46 children in total.

18 This necessarily involves,
19 Mr. Commissioner, the calling of evidence concerning
20 the complete clinical condition and history of the
21 relevant children prior to their deaths. It is
22 our hope that this medical evidence, if I can thus
23 describe it, will commence in the very near future
24 and, depending on the scheduling of witness and the
25



1
2 completion of cross-examination this week, may start
3 as early as Thursday of this week and certainly will
4 continue next week.

5 It was never the intention of
6 Commission Counsel to represent or rely upon the
7 case summaries included in the Statement of Prima
8 Facie facts as being completely accurate or
9 sufficiently detailed.

10 The purpose of including summaries
11 in the statement at the time of its preparation
12 and now is merely to provide a starting point to
13 counsel who have not yet had access to the Hospital
14 medical charts and records and to assist in providing
15 an introduction to the detailed medical evidence
16 which is to follow.

17 You will appreciate, Mr. Commissioner,
18 that a number of counsel in the room currently have
19 access through their client to the medical charts
20 and records that are at issue.

21 Commission Counsel has arranged to
22 copy the relevant medical charts and records and
23 they will be introduced as an exhibit before you
24 at the outset of the medical evidence to which I have
25 just referred.



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Commission Counsel are of the view,
in light of these comments, that with our intention
regarding future evidence clearly understood,
these purposes can still be accomplished by leaving
these case summaries in the Statement of Prima Facie
Facts, recognizing that subsequent new witnesses
may choose to disagree with certain of the facts
contained in the medical case summaries or to
expand upon same, or the Statement itself, as evidence
progresses, may well require amendment, as you,
yourself, have noted, Mr. Commissioner, from time to
time.

The fourth substantive area of
submission, Mr. Commission, which I wish to address
is that raised, you will recall, by Mr. Ortved on
June 21st concerning those sections of the Statement
which deal with the mortality reviews conducted by
the Hospital. The facts relating to these reviews
are found in Part 5 of the Statement of Prima Facie
Facts.

Mr. Ortved suggested to you in this
regard, sir, that the information contained in this
Statement and drawn from the Dubin Report was a
mistranslation in certain instances of the findings
from the Dubin Report itself and suggested further



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that some of the facts in the Dubin Report, and thus referred to in the Statement of Facts, were not consistent with the matters recorded in the Hospital minutes of these meetings.

The minutes of these meetings are not, unfortunately, currently part of the public record. Accordingly, at the time of the preparation of the Statement of Prima Facie Facts Commission Counsel could not have reference to their contents as a source of uncontraverted facts. It is intended that those minutes will be introduced in evidence and that they will be subject to testing under cross-examination when reviewed by other counsel.

Similarly, Commission Counsel do not, and did not, have access to, and are not aware of all of the information made available to the Dubin Review Committee upon which their findings concerning the Hospital mortality reviews were based.

Mr. Ortved has provided Commission Counsel with detailed comments in writing, as have other counsel, concerning the Hospital mortality reviews. Some of these comments are based on the interpretation of the contents of the Dubin Report and, in other instances, they are based directly



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2 on, and find support in, the minutes themselves.

3 We propose, as I will outline
4 further, to file Mr. Ortved's comments in this
5 regard as an exhibit before you today, together
6 with the written comments received from all other
7 counsel.

8 Finally, Mr. Commissioner, as I
9 mentioned more than once, we have now received
10 and reviewed written comments from various counsel
11 concerning the Statement of Facts. Not all counsel
12 felt it appropriate to deliver comments in this
13 regard. Copies of the comments that we have
14 received have now been circulated and made avail-
15 able to all other counsel.

16 The comments received fall into
17 one of three categories, Mr. Commissioner; the
18 first, allegations that the facts contained in,
19 and drawn from, the source documents are inaccurate
20 or untrue, notwithstanding that they are recorded
21 as factual in the source documents, be it the Dubin
22 Report, be it the Reasons for Judgment of His
23 Honour Judge Vanèck or be it the transcripts of
24 evidence in the Preliminary Inquiry concerning
25 Susan Nelles.

The second category of comment, again



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if I can describe it in that way, concern allegations that the facts contained in, and drawn from, the source documents are incomplete or misleading.

Finally, the third category of comment received with respect to the Hospital mortality reviews, that the facts contained in the Dubin Report are, in some instances, inaccurate and, in other instances, may have been - and I take it from my friends - inadvertently misinterpreted in the preparation of the Statement of Prima Facie Facts.

In some instances, Mr. Commissioner, counsel, in delivering these comments, have drawn the attention of Commission Counsel to specific references in the public record which support their contentions. In the vast majority of cases, sir, undoubtedly due to the constraints of time and the overwhelming nature of the task, the specific sources have not been drawn to our attention and, in lieu thereof, information has been provided to Commission Counsel that emanates directly from parties having standing before you without reference to the public source documents.

This latter situation presents various difficulties for Commission Counsel. For



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2 example, where a counsel has indicated that his or
3 her client believes thus and so and that does not
4 appear to be supported on the public record, or at
5 least our attention has not been drawn to that
6 part of the public record which does support that
7 information, we cannot properly accept the informa-
8 tion at this stage without more as the basis for
9 amending the Statement of Prima Facie Facts. In
10 other words, that particular individual's informa-
11 tion may indeed be accurate but must be adduced,
12 in our submission, in the usual way in viva voce
13 evidence, where the information is relevant or
14 otherwise supported by the public record as it now
15 stands. It may well be, Mr. Commissioner, that
16 certain of the evidence adduced before His Honour
17 Judge Vaneck at the preliminary hearing or certain
18 of the matters reported in the Dubin Report were
19 incorrect or incomplete. At this early stage of
20 the Commission's hearings, however, we, as Commission
21 Counsel, in my submission, cannot assess the
22 accuracy or inaccuracy of such facts unless some
23 evidence of facts to the contrary, or supplemental
24 facts, exist on the public record.

25 Accordingly, Mr. Commissioner,
Commission Counsel propose the following:



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First, that an Addendum to the Statement of Prima Facie Facts prepared by Commission Counsel be filed with the Statement itself as an exhibit before you.

This Addendum lists, paragraph by paragraph, those facts contained in the Statement of Prima Facie Facts which have now been put in issue by any party through their counsel. It further lists those parties who have so lodged an objection.

The purpose of the Addendum, Mr. Commissioner, was not to cure the deficiencies which other counsel feel exist in the Statement of Prima Facie Facts but, rather, to provide in one convenient source a compendium of those facts which now appear to be in issue, together with an indication of those counsel who disagree with the facts as stated.

The Addendum further lists, again paragraph by paragraph, those paragraphs which Commission Counsel have now been informed are incomplete or inaccurate and in respect of which Commission Counsel presently intend to call evidence. There may well be others as the hearing progresses, sir.

The Addendum also constitutes a



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caution, Mr. Commissioner, to those who will be reviewing it and the Statement of Prima Facie Facts that the facts contained in the Statement are provided as an initial framework only and that some may require amendment, deletion or correction as evidence is adduced at these hearings.

Secondly, Mr. Commissioner, we propose that the written comments received from all counsel concerning the Statement of Facts be marked as a bundle as an exhibit before you.

Thirdly, we propose that the Addendum, the Statement of Prima Facie Facts and the written objections and comments received from counsel be released to the public upon request as a package.

In the best of all worlds, Mr. Commissioner, given unlimited time and the luxury of a limited number of tasks to be accomplished, a detailed review of the Statement and its contents could be undertaken by Commission Counsel with counsel for all interested parties and a revised version produced. A brief review of the written comments received from various counsel, however, would quickly demonstrate that this would not be an easy or speedily accomplished task.

For example, Mr. Commissioner, in



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2 respect of any particular paragraph in the Statement,
3 we have received suggestions from some counsel that
4 the contents of that paragraph are accurate and,
5 conversely, in respect of the very same paragraph,
6 we received submissions from other counsel that the
7 contents of the paragraph are inaccurate. So,
8 there are discrepancies, as one would expect, from
9 various counsel in the comments that have been
received.

10 We would submit, Mr. Commissioner,
11 that the predominant interest of the Commission and
12 of the public at this stage is to press forward
13 with the hearing of relevant evidence. As that
14 evidence unfolds, certain facts will be clarified;
15 others negated and new ones established. Where
16 facts contained in the Statement of Prima Facie
17 Facts are contradicted, enlarged upon or clarified
18 by facts adduced in evidence before you, that
19 evidence will clearly take precedence over those
20 facts contained in the Statement which may have been
impugned which have been put in issue.

21 I would propose, therefore, Mr.
22 Commissioner, that you now accept as exhibits the
23 Addendum to which I have referred and the written
24 submissions which Commission Counsel have received
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from other counsel. You will recall that the Statement of Prima Facie Facts was accepted by you as an exhibit on June 21st, although not for public dissemination.

I will propose, finally, that you authorize the release of each to the public, together with the Statement itself.

THE COMMISSIONER: Yes. Thank you, Miss Cronk.

I will hear any comments that anybody has but, before I do that, I just want to make it clear that the purpose of the Statement of Facts, as I understood it, was to avoid unnecessary evidence; that is Paragraph 1 of the Terms of Reference of this Commission. I don't feel bound by anything in the Statement of Facts if the evidence discloses something different, and I will act upon that evidence; not upon what is in the Statement of Facts. However, the Statement of Facts does serve two purposes; one, the purpose I want; namely, to avoid unnecessary evidence, and, two, the purpose, if you want more on that, is to give you some background information which, perhaps, you have already acquired that.

Any comments from anyone?

Yes, Mr. Tobias.



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MR. TOBIAS: Mr. Commissioner, as I understand the original objections of various counsel, the primary concerns seem to be that, based on the Prima Facie Statement of Facts, Commission Counsel might not call certain evidence, and that was set out in the Statement of Facts.

Certainly, given the safeguards the Commission Counsel have just expressed and given your own comments about the evidence taking precedence over the document, it would seem that the other concern that you might act on a given fact has been answered and we do not have to be concerned with it anymore.

I would suggest that perhaps those documents be released to the public at this time and if any specific counsel is concerned that an area that they are particularly interested in will not be proved by viva voce evidence because it has been handled in the Prima Facie Statement of Facts, then that counsel can bring a motion to you, a notice to Commission Counsel that they would like that evidence called viva voce and that they, in effect, dispute that particular fact, and I think, subject only to that caveat, I would support Miss Cronk's submission.



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THE COMMISSIONER: There will also come a time when each counsel will be asked whether he wishes to call any evidence --

MR. TOBIAS: Yes, I'm aware of that as well, and I believe that that provides an even further safeguard.

THE COMMISSIONER: Yes. Right.
Any further comments?

MR. BOGART: Mr. Commissioner, I would like to make this comment about the business of your acting on evidence, sir. Obviously, we are very sympathetic to avoiding unnecessary evidence and to move this matter along as quickly as possible.

But there is the question of onus, I believe, in terms of who has the onus to call the evidence when the facts are put into dispute and it is certainly our position that the onus should not be on counsel but, rather, should be on Commission Counsel when something is put in dispute that is relevant.

I believe that my remarks are consistent with remarks that you made the opening day of the hearing, sir.

THE COMMISSIONER: Yes, I understand that. I took a rather stern stand on onus at the



1
2 beginning and I am already wilting all over the
3 place; so don't worry too much about it.

4 As a matter of fact, I suggest,
5 throughout your whole career in Law, don't worry
6 too much about onus. Judges cheat on onus all the
time!

7 MR. BOGART: Just so long as you
8 don't cheat in this hearing, sir!

9 THE COMMISSIONER: Any other comments?

10 All right, then, you seem to be
11 almost unanimously approved, Miss Cronk, so you can
12 put them all in.

13 MISS CRONK: That is a higher hope
than I had, Mr. Commissioner.

14 THE COMMISSIONER: How are we going
15 to do it, though? I think we have already one in
16 as '3' and one in as '3A'.

17 MISS CRONK: Yes, we do, Mr.
18 Commissioner. The Statement of Facts was marked as
19 Exhibit 3. The written comments received --

20 THE COMMISSIONER: What about putting
21 all the written comments starting in any order you
22 like; 3B, 3C, whatever you like, and when you come
23 to the end of it, put the Addendum in as '3', let us
say, 'K'.

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MISS CRONK: You anticipated me, sir,
as usual.

THE COMMISSIONER: Good. All right,
you just call them out, then.

MISS CRONK: Exhibit 3A are the
written submissions already received and filed from
counsel for the Hospital.

Exhibit 3B, I would ask you accept
submissions received on behalf of certain doctors
at the Hospital for Sick Children as represented by
Mr. Ortved.

Exhibit 3C, Mr. Commissioner, I would
ask you to accept written submissions received from
Mr. Strathy on behalf of Phyllis Trayner.

Exhibit 3D, Mr. Commissioner, I would
ask you to accept written submissions received from
Messrs. Jackman and Goodman with respect to the
Statement of Prima Facie Facts on behalf of Marianna
Christie.

Exhibit 3E, Mr. Commissioner, I would
ask you to accept written submissions received from
Mr. Percival's offices on behalf of the Metropolitan
Toronto Police Force.

Exhibit 3F, Mr. Commissioner, written
submissions received from Messrs. Symes, Kitley and



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McIntyre on behalf of the Registered Nurses' Association of Ontario and named individuals whom they also represent.

Exhibit 3G, written submissions received from, again, counsel on behalf of the Hospital, Messrs. Cameron, Brewin and Scott. These are supplementary submissions received from Mr. Scott, as they then were.

Exhibit 3H, Mr. Commissioner, written submissions received from Messrs. Stykeman and Elliott on behalf of Susan Nelles.

Finally, sir, written submissions received from counsel on behalf of the Ministry of the Attorney General et al.

THE COMMISSIONER: That would be 3I we have got down to, I guess.

MISS CRONK: The final exhibit in the bundle, sir, that I would ask you to accept, is the Addendum itself, which will be 3J.

THE COMMISSIONER: 3J is the Addendum.

MISS CRONK: I note, in reviewing the exhibits, which I will now provide to you, sir, that I am missing a copy of the submission received from the Ministry of the Attorney General. I will provide that to the Registrar this morning.



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THE COMMISSIONER: Thank you.

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--- EXHIBIT NO. 3B: Written submissions by Mr. Ortved on behalf of certain doctors at the Hospital for Sick Children.

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--- EXHIBIT NO. 3C: Written submissions by Mr. Strathy on behalf of Phyllis Trayner.

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--- EXHIBIT NO. 3D: Written submissions by Messrs. Jackman & Goodman on behalf of Marianna Christie.

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--- EXHIBIT NO. 3E: Written submissions by Mr. Percival on behalf of the Metropolitan Toronto Police Force.

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--- EXHIBIT NO. 3F: Written submissions by Messrs. Symes, Kitley & McIntyre on behalf of RNAO and named individuals.

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--- EXHIBIT NO. 3G: Written submissions by Messrs. Cameron, Brewin & Scott on behalf of the Hospital for Sick Children, Supplementary.

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--- EXHIBIT NO. 3H: Written submissions by Messrs. Stykeman & Elliott on behalf of Susan Nelles.

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--- EXHIBIT NO. 3I: Written submissions by counsel for the Ministry of the Attorney General et al.

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--- EXHIBIT NO. 3J: Addendum to the Statement of Prima Facie Facts.

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MISS CRONK: In addition, sir, Mr.

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Lamek reminds me to indicate that copies of the

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Addendum, as well as copies of the written objections

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and comments received, have now been circulated

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amongst all counsel.

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THE COMMISSIONER: Yes. Thank you.

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MISS CRONK: Sir, on Thursday last,
Dr. Ellis was testifying before you. I would recall
Dr. Ellis to the stand at this time.

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MR. TOBIAS: Over the weekend, I have
had some time to reflect again on a subject that
seems to beset us, and that is the subject of the
Atlanta Report.

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THE COMMISSIONER: Could you just hold
that until this afternoon.

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MR. TOBIAS: Yes.

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THE COMMISSIONER: I think there will
be a statement this afternoon on the Atlanta Report
which may put most of your problems to rest.

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MR. TOBIAS: Fine. Thank you.

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THE COMMISSIONER: Yes, Mr. Bogart.

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MR. BOGART: I just had a question
about the medical records which Miss Cronk referred
to a few moments ago, which she said would be marked
as exhibits. I assumed that we will be provided with
copies of those medical records and, if we are going
to get into them this week, I wonder if I might ask
Mr. Lamek and Miss Cronk, through you, if we could
be provided with those records before they are marked
as an exhibit. That would be, I think, very useful.



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THE COMMISSIONER: There is an unbelievable logistical problem about records; so, perhaps Mr. Lamek will tell us all about that.



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MR. LAMEK: I wouldn't say all my problems but certainly there is a very substantial physical problem in re-producing in sufficient quantities the number of medical records that we're talking about. I can only say that people are working literally night and day to accomplish that end. I think what is likely to develop is something like this: that the first of the medical men who goes into the box to discuss the charts of the particular children which he has reviewed will be Dr. Rowe, the head of the Cardiology Division of The Hospital for Sick Children. It may be that by the time Dr. Rowe goes into the box, which I suspect may be later this week, that copies of all the charts will not yet be available for distribution, but as a matter of priority, those which he will discuss first will be available and I would expect that the evidence of Dr. Rowe will take a sufficient length of time that counsel will have ample time to consider the reports as they become available and are distributed and marked as exhibits to prepare properly for cross-examination.

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I would like to have things in counsel's hands ahead of time, Mr. Commissioner. The practical exigencies of the situations sometimes make that



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2 impossible, but I would ask counsel to be patient
3 with me and sympathetic with those problems and
4 I'll get the stuff to them just as soon as possible.

5 THE COMMISSIONER: I take it we
6 now have no legal problem, am I right, about
7 distribution of the medical reports?

8 MR. LAMEK: Mr. Commissioner, the
9 legal problem of our acquisition of the charts
10 I think has been satisfactorily dealt with. We
11 have the charts as a result of the execution of a
12 search warrant for them under the powers given under
13 the Public Inquiries Act.

14 I see no impediment to our marking
15 those documents as exhibits for the purposes of this
16 Commission. There may notionally be some problem
17 about the prior release to counsel, but it may be
18 that is a non-existent problem anyway because of
19 their unavailability until they are able to be
20 marked. That problem may disappear even if it is a
21 problem.

22 I should be clear, Mr. Commissioner,
23 Miss Cronk properly reminds me, that when I say
24 that the charts were obtained under the execution
25 of a search warrant at the Hospital, that there was
complete co-operation by the Hospital in that regard



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but it was properly concerned that there be not
improper distribution of the medical charts.

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THE COMMISSIONER: Yes. Of course,
I take it that those counsel acting for parents
already have the charts of their own?

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MR. LAMEK: With one exception and
that is I think Mr. Manning's latest set of clients.
He is now acting for, I think, the parents of the
Murphy child who died in the period with which we
are concerned, Paul Murphy, and that chart is now
being copied. But otherwise, Counsel acting for
parents of children have received copies of the
charts of those children.

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THE COMMISSIONER: Well, now, how
does that resolve your problem. I mean, it's the
best we can do.

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MR. BOGART: Yes, and for that I
thank you, sir and thank you, Mr. Lamek.

MR. PERCIVAL: Mr. Commissioner?

THE COMMISSIONER: Yes.

MR. PERCIVAL: I think Mr. Lamek
had indicated to us there was going to be one week
during the summer that Your Lordship might not be
available.

THE COMMISSIONER: Yes, I have some



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other duties on, I think it is the -- I know it includes the 12th of August because I have them every year and that's my son's birthday. I have missed it every year now for the last five years. So, it will be whatever week, I think it is the 8th, is it?

MR. PERCIVAL: The week starting Monday the 8th of August.

THE COMMISSIONER: Yes.

MR. PERCIVAL: So, that's the week you many not be sitting?

THE COMMISSIONER: Well, I can't. I find it difficult, I'm in Regina, so, it's impossible. I suppose if there is enough of a row, we might take off some other time but only if there is enough of a row. I mean, I would like to go on throughout the summer and get it over with as soon as possible, but we'll see.

MR. PERCIVAL: Thank you, sir.

THE COMMISSIONER: Anything else?
All right, Ms. Cronk.

MS. CRONK: Could I recall Dr. Ellis to the stand at this time, Mr. Commissioner?

DR. GRAHAM ELLIS, Resumed

MS. CRONK: Mr. Commissioner, you



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2 will recall that on Thursday last I completed my
3 examination in chief of Dr. Ellis. Over the weekend
4 he, through his counsel, have been kind enough to
5 provide Commission Counsel with copies of various
6 documents to which he referred in his evidence and,
7 with your indulgence, I propose very briefly to
8 put a number of questions to Dr. Ellis to identify
9 those documents, concerning them, and I will have
10 completed my examination in chief.

11 THE COMMISSIONER: Yes, all right.

12 FURTHER DIRECT EXAMINATION BY MS. CRONK:

13 Q. Dr. Ellis, do you recall, sir,
14 giving evidence on Thursday last concerning the
15 therapeutic and toxic ranges of digoxin considered
16 by you and your lab to apply during the period
17 July, 1980 to March, 1981? Do you recall giving
18 that evidence?

19 A. Yes, I do.

20 Q. All right. And you referred
21 us specifically, Dr. Ellis, to an Article published
22 in 1978 in the Journal of the American Medical
23 Association in that regard?

24 A. Yes.

25 Q. And I believe, correct me if
I'm wrong, sir, you referred us as well to an



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2 extract from the Resident's Handbook, Pediatrics,
3 published in 1979?

4 A. Yes.

5 Q. Do you recall that, sir?

6 A. Yes.

7 Q. And that Article you indicated,
8 I believe you were reading from the Resident's
9 Handbook at that time, recorded a number of values.
10 Do you have with you a copy today of the extracts
11 from the Resident's Handbook?

12 A. I have a copy of that, yes.

13 Q. You do, all right. The
14 extract from the Handbook, Dr. Ellis, page 365.
15 Perhaps you can just look at the one I have and
16 ensure that we're looking at the same extract.

17 THE COMMISSIONER: What's happening
18 with the Article, are we making that an exhibit?

19 MS. CRONK: Yes, I'm coming back to
20 that.

21 THE COMMISSIONER: Was that one of
22 the ones that we reserved, do you remember?

23 MS. CRONK: No, sir, I don't believe
24 that the article was a reserved exhibit. We did
25 reserve an exhibit number for various requisition
forms.



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THE COMMISSIONER: The requisition
forms, all right.

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MS. CRONK: I'll be returning to
the Article with your indulgence in just a few
moments.

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THE COMMISSIONER: Oh, all right.

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MS. CRONK: Q. Dealing first then,
Dr. Ellis, with the extracts from the Residents'
Handbook, and Mr. Commissioner, I believe that
copies of this have been provided to all other
counsel this morning. That extract indicates under
the word "Digoxin" various reference values to which
you referred us in your evidence on Thursday last.
Is that correct, Dr. Ellis?

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A. Yes.

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Q. Can you help, sir, because
I neglected then to ask you, did those values apply
to infants and adults or to both or to either?

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A. I think the Journal of the
American Medical Association related mainly to
adults, and then there are subsequent qualifiers
after this relating to infants.

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Q. All right.

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A. And this was the information
that we had at that time.



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Q. With respect to the qualifiers, are you referring to the notes set out in the extract from the Residents' Handbook?

A. That's correct.

Q. All right. Now, dealing with those notes specifically, the first is a note concerning the serum concentration ---

THE COMMISSIONER: Could I have a copy of that?

MS. CRONK: Oh, I'm sorry, sir.

THE COMMISSIONER: If there is one available that I could have. Thank you.

MS. CRONK: I apologize, Mr. Commissioner.

THE COMMISSIONER: All right.

MS. CRONK: Q. Dr. Ellis, referring to the first note which appears below these reference values, that note refers to the serum concentration above which toxicity becomes more likely and indicates that that concentration level is not clearly defined and varies between individuals in quoting:

"In some studies digoxin above 2.5 nanograms per millilitre or above 2.0 nanograms per millilitre was



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"potentially toxic."

There are in addition three other notes set out in the extract from the Handbook with respect to the values.

Are the values as recorded in the Handbook that we are now looking at, values which you understood to apply to infants during the period July, 1980 to March, 1981?

A. Yes, they are. There is a very slight modification I think from the original American - Journal of the American Medical Association article, which I think I gave you a copy of?

Q. You did, sir.

A. And I think that in that particular article they listed 2.0 to 3.0 as being overlap, towards the end of the article.

Q. As compared to the overlap of 2.5 to 3.0.

A. 3.0.

Q. Indicated in the extract?

A. That's right. This document was essentially for the residents' use and in order to avoid any confusion as to what a level of 2.3 might really be, we elected to use this value of



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2.5 to 3 for the overlap region.

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Q. Thank you. And you have told me that those reference values were ones that you considered to apply to infants during this time period. Did you consider them as well to apply to adults?

A. No, I think I indicated to you these related mainly to adults.

Q. All right.

A. Okay.

Q. That's what I'm a little uncertain of, Dr. Ellis. Are there reference values contained anywhere else in the Residents' Handbook that are particular for digoxin for infants as opposed to values that we see on page 365?

A. I think these are the only ones but I have referred here to Pediatrics 59/1977 and also the Journal of Pediatrics, 1978 in Note 2.

Q. Yes.

A. So, anyone wanting further details could go to those.

Q. All right. To your knowledge today, sir, does that Article noted in Note 2 indicated different reference values for infants than those disclosed in the extract from the Handbook?



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A. I don't know whether that related to 2.0 or 2.5 or even higher values than that.

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Q. All right.

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A. For the premature infants.

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Q. For your own purposes in your lab, sir, in running samples on children during the period July, 1980 to March, 1981, did you use or have reference to these reference values contained in the handbook or to others that may be set out in the articles referred to in the notes?

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A. Yes, at that time we would regard up to 2.5 nanograms per mill as being satisfactory. In samples taken six to eight hours after the digoxin dose. I later learned that the Hospital for Sick Children the dosage of digoxin is given 12 hourly and in a number of centres they prefer to take a sample for the next dose. In those centres, I think the value of 2.0 was taken as a hospital value at some stage during 1982 in consultation with clinical pharmacology and therapeutic drug monitoring program and the cardiologists.

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Q. In your centre then, Dr. Ellis, in the Hospital for Sick Children during the period that we're talking about, do I take your evidence



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to be that anything up to a 2.5 nanogram per milli-
litre level was considered satisfactory?

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A. Yes, with the qualifier of
Note 1.

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Q. All right. Note 1 from the
extract of the Handbook?

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A. Yes.

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Q. And anything above would be
considered to be in the toxic range?

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A. Yes.

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Q. And that would be in both
instances that was the case for infants?

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A. Well, as indicated in Note 2
infants may have higher levels than 2.5 but not
show signs of toxicity.

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Q. All right.

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Mr. Commissioner, could we mark that
as the next exhibit. The exhibit number I believe
is Exhibit No. 16.

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THE COMMISSIONER: Is that the
Resident's extract?

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MS. CRONK: Yes.

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THE COMMISSIONER: That will be
Exhibit 16.

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3 ---EXHIBIT NO. 16: Extract from Residents'
Handbook, page 365.

4 THE COMMISSIONER: All right,
5 thank you.

6 MS. CRONK: Thank you.

7 THE COMMISSIONER: Will we use this?

8 MS. CRONK: I will provide
9 Mr. Bogart with another copy, sir, I seem to be
10 short on my copies today.

11 THE COMMISSIONER: Fine.

12 MR. BOGART: Yes, that's fine.

13 MS. CRONK: Thank you.

14 Q. Dr. Ellis, one other question
15 with respect to the contents of the reference values
16 set out in the Handbook. Can you help me, Dr. Ellis,
17 because I believe you told us on Thursday last that
18 you assisted in the preparation of that chapter of
19 the Handbook which pertained to biochemistry?

20 A. Yes.

21 Q. All right. And does this
22 extract come from that section of the book?

23 A. Yes, it does.

24 Q. All right. Can you tell me
25 why reference values particular to adults based on
the then existing literature would be contained in



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the handbook that was intended for residents of
Pediatrics?

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A. Simply because this particular
article seemed to be one where someone would give
a clear indication as to what they regarded as
under digitalized, what they regarded as optimal,
what they regarded as overlap and what they regarded
as toxic.

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Many of the other references were
really very much vaguer and they would have quite
wide ranges of areas where toxicity may or may not
occur.

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Q. Insofar as you were aware,
Dr. Ellis, at the time this Handbook was in prepara-
tion, was there a clear delineation in the literature
of reference values in a format similar to this
for infants, particular to infants?

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A. I don't know what is stated
in Pediatric Clinical Chemistry, a book by Meites.
I don't know what value is there. There would
probably be a number of ranges stated there.

Q. All right, thank you, sir.

You referred us as well to the
Article from the Journal of the American Medical
Association. I have before me a copy of an article



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which you provided to me through your counsel dating
from June of 1978, an article by Dr. James Doherty
entitled "How and When to Use the Digitalis Serum
Levels". Is that the Article to which you referred
us previously?

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A. Can you show me that, please?

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Q. Yes, certainly.

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A. Yes, that's correct.

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Q. Do you have a copy of that

before you, Dr. Ellis?

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A. I may have.

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Q. I am sorry, sir, do you have a copy of that article?

A. I don't have a copy immediately to hand.

Q. I refer you, Dr. Ellis, to page 3 of the article, near the bottom of the first column, the paragraph beginning with the language:

"Each laboratory should establish its own limits ... "

Do you see where I am reading, sir?

A. Yes, page 2596.

Q. Was that the passage in this article to which you were referring when you gave us the reference values indicated?

A. That is correct, yes.

Q. And could we mark that, Mr. Commissioner, as the next exhibit, I believe that is Exhibit 17.

--- EXHIBIT NO. 17: Journal of American Medical Association (Extract).

Q. I draw your attention as well, Dr. Ellis, to the introductory paragraph to that article which indicates:

"The indications for measuring serum digoxin levels are a suspicion



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"of digitalis intoxication and the need to know the status of digitalization. Pitfalls of interpretation include time of serum sample relative to time of last digitalis dose; age of patient; atrial arrhythmia, electrolyte disturbances, disease state of the patient, recent radioisotopes on board ... "

And stopping there for a moment, can you help me, Dr. Ellis, as to what the reference to "recent radioisotopes on board" means?

A. Yes. If a child had a radioisotope procedure, a scan of some sort, then if blood were taken immediately following that scan with a radio nucleoid then there is a possibility that erroneous results might be obtained.

Q. The introduction continues in reciting a number of factors that the author considers to be pitfalls of interpretation including:

" ... abnormal absorption or metabolism and laboratory error. The serum digoxin level is a useful clinical tool but only when employed with good judgment, not every patient receiving digitalis requires the measurement of a blood level."



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Dr. Ellis, dealing with those matters described by the author to be pitfalls of interpretation with respect to the digitalis serum levels, do you agree that those are factors to take into account once an assay result for digitalis has been obtained?

A. Yes, I felt this was a good summary, this is why I cited this particular article.

Q. Thank you. Recall as well, Dr. Ellis, that we discussed last Thursday the Form of Requisition which was in use in your Laboratory for the period July 1980 to March 1981 and you testified as well concerning the Form of Requisition that was introduced upon the introduction in the Hospital of the Therapeutic Drug Monitoring Program, both initially and then in its revised state. Do you recall giving evidence in respect of that?

A. Yes.

Q. I am showing you now, Dr. Ellis, a Form of Requisition which has been provided to me through your Counsel. I would ask you to tell me, is this the Form of Requisition that was in use in your Laboratory during the period July 1980 to March 1981?



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A. This is essentially the Form of Requisition. There are very slight cosmetic differences to this particular one, one or two compounds were not on the original Requisition for use at that time, essentially it is the same.

Q. Do you have another copy of that, sir, with you today?

A. There was one clipped on the back, it was a photocopy of a used Requisition but is essentially similar to this.

MS. CRONK: Could that be marked as the next exhibit, Mr. Commissioner, and that I believe was a reserved number.

THE COMMISSIONER: I thought the new ones were reserved, do you have the new ones as well?

MS. CRONK: Yes I do, sir, I was going to propose that the three be marked as 15A, 15B and 15C.

THE COMMISSIONER: Yes, all right, then we will mark this one 15A. I don't want to be too difficult, but we reserved 15 itself for Requisition Forms and I thought they were new requisition forms, am I wrong? You are going to have three of them.

MS. CRONK: There are three in total, sir.



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THE COMMISSIONER: Yes.

MS. GOODMAN: May I ask that Ms. Cronk describe what she is referring to of the three.

MS. CRONK: I am just coming to that, Ms. Goodman. There are three Requisition Forms and my recollection, Mr. Commissioner, is that the number was reserved for all three, the one from the July 1980 to March 1981 period.

THE COMMISSIONER: All right, we have got them chronologically, can we mark this 15A.

MS. CRONK: That is correct, sir.

THE COMMISSIONER: All right.

--- EXHIBIT NO. 15A: Requisition Form:
"Clinical Chemistry".

MS. CRONK: Q. For the ease of other Counsel, Dr. Ellis, is the Requisition Form which we have just marked headed "Clinical Chemistry" with a number on the left hand side of the page?

A. Yes.

Q. Can you tell me, Dr. Ellis, where on that Form an assay request for digoxin would be indicated, where would the word "digoxin" appear, if at all?

A. Yes. This would be indicated in "other requests". The most common requests are



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listed by name, the slightly less common ones, there is a space available for them.

Q. What are the most common ones that are listed on that form, what section of the form are you looking at?

A. Sodium potassium chloride on the left-hand side of this Form.

Q. And on the right-hand side of the Form, Dr. Ellis, as I recall it there are four boxes beside which appear the words, at least the abbreviations, or what I take to be the abbreviations starting first VEN, can you tell me what that refers to?

A. Yes. This is a venous blood sample.

Q. And then ART?

A. An arterial blood sample.

Q. And CAP?

A. A capillary blood sample.

Q. And CFF?

A. Cerebro spinal fluid.

Q. Do I take it then that the completion of that box on this form would constitute an indication in a laboratory of the nature of the sample that had been obtained?



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A. Yes. There is also a box underneath it labelled "other".

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Q. And in the normal course of events if the four particular boxes were not completed the referring physician or the physician requesting the assay would have the option of completing the other category to indicate what kind of sample, at least the site of the sample that was being sent to the laboratory, is that correct?

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A. Yes.

Q. And the second Form of

Requisition that has been provided to me, Dr. Ellis, through your Counsel, is a Form that I have been told or advised was introduced with the introduction of the Therapeutic Drug Monitoring Program. It is entitled "The Hospital for Sick Children, Department of Clinical Biochemistry, Therapeutic Drug Monitoring Requisition", do you have a copy of that with you today, sir?

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A. I don't, no.

Q. Now, to distinguish that Form,

Dr. Ellis, from a Form that I will introduce in a moment or two, am I correct that on that form there is a space for completion of information concerning one assay and one assay only?



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A. No, you have given me the one labelled "Drug A" and "Drug B", this is the most current one.

Q. And I have referred you to the second one.

A. Yes.

MS. CRONK: I apologize, Mr. Commissioner, I can tell there is magic to this copying to be sure there are sufficient copies.

Q. To identify this Requisition Form, Dr. Ellis, from the subsequent one, am I correct that this form provides space for information with respect to one assay and one assay only?

A. That is correct, yes.

Q. And can you confirm for us, sir, that is the form that came into use in the laboratory with the introduction of the Therapeutic Drug Monitoring Program?

A. Well this was mainly used for Dr. Soldin's laboratory when the Therapeutic Drug Monitoring Program came in.

Q. Subsequently, after the introduction of the Therapeutic Drug Monitoring Program, when you again became involved in running digoxin assays, was this the Form of Requisition that was then in use in your Laboratory?



E.9

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A. I think it may have been this one at that time, yes.

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Q. And in large block letters appearing on that Requisition Form, Dr. Ellis, is the indication "The analysis will not be performed unless this information is provided", do you see that, sir?

7

A. Yes.

8

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Q. Can you tell the Commissioner briefly what that refers to?

10

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A. Well basically the information in relation to the medication prescribed and the drug analysis requested.

12

13

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Q. If that information was not contained in the boxes set out for its inclusion would the assay in fact be performed in your Lab?

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A. I think it would be best to discuss this with Dr. Soldin because I didn't design this Requisition and he did.

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Q. Well, let me understand that, and certainly I will do that, Dr. Ellis. Once you became re-involved in performing digoxin assays, after the introduction of the Therapeutic Drug Monitoring Program, if the information required by this form was not provided to your Lab would the assay be proceeded with?



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A. Well, we essentially receive samples that have been prepared for us by the Therapeutic Drug Monitoring Laboratory, so they are responsible for receipt of the samples, for the centrifugation of the samples and the passing of serum samples to be analyzed and we just analyze the samples and then we handed them back to be reported.

Q. Would you ever receive this Requisition Form in your Lab then at all?

A. This would have come into the Lab, yes.

Q. And the information that is requested in that box, as I recall it, Dr. Ellis, is firstly an indication of the particular analysis that is being requested?

A. Yes.

Q. And would that be the appropriate place on the form for the requesting physician to insert the word "digoxin assay"?

A. Yes.

Q. And secondly, there is an indication for the time of the last dose to be indicated?

A. Yes.

Q. And thirdly for the amount of the last dose?



E.11

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A. Yes.

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Q. And fourthly, an indication as to the type of specimen?

4

A. Yes.

5

6

Q. I take that to be the type of sample?

7

A. Yes.

8

9

Q. And then fifthly, an indication of the time that the specimen or sample had been collected?

10

11

A. Yes.

12

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Q. And finally an indication for completion for the date the specimen and sample had been collected?

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A. Yes.

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Q. And all of that is contained in the box on the Form which indicates that the analysis will not be performed unless that information is provided?

19

A. Yes.

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MS. CRONK: Could that be marked as the next exhibit?

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THE COMMISSIONER: Yes, 15B. Has it got the same title, that is the Drug Monitoring Requisition?



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MS. CRONK: I am sorry, sir, this is the first Requisition that is entitled "Therapeutic Drug Monitoring Program".

THE COMMISSIONER: It has the same title?

MS. CRONK: Yes, it does, sir.

THE COMMISSIONER: Is there some way we can distinguish it?

MS. CRONK: Single assay.

--- EXHIBIT NO. 15B: Requisition Form: "Therapeutic Drug Monitoring Program, Single Assay".

MS. CRONK: Q. Dr. Ellis, I have provided you with a copy of the third Form of Requisition that has been provided to me by your Counsel, it is similarly entitled in the same way as Exhibit 15B is, but on the face of it as I look at the Form and perhaps you can confirm whether I am interpreting the Form correctly or incorrectly, there is space on the face of the Form itself for inclusion of information with respect to one or two assays?

A. Yes.

Q. So I take it that that Form, if completed, could request a digoxin assay and in addition an assay of potentially one other drug but only one other drug?



E.13

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A. Yes.

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Q. Is that correct?

4

A. Yes.

5

Q. And if an assay was requested

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on more than two drugs, inclusive of digoxin, would another Requisition other than that Form have to be completed?

8

A. I am not sure whether Drug B

9

could be drugs like anticonvulsion drugs or whether

10

specifically phenobarbitone would have to be called

11

for individually and it may be a particular profile

12

of drugs. Digoxin as Drug A, let's say, plus profile of drugs Drug B.

13

Q. Yes. If an entirely different

14

category of drug assay was being requested would that require completion of a separate second Requisition Form?

15

16

17

A. I think it is best to discuss

18

that with Dr. Soldin.

19

Q. You are not familiar with

20

whether or not that was required?

21

A. No. There is a revision note

22

on the bottom left-hand corner Revised, I think it is O2 or O3, 1983, so this has been in use recently.

23

MS. CRONK: Could that be marked as

24

the next exhibit, Mr. Commissioner?

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E.14

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--- EXHIBIT NO. 15C: Requisition Form:
"Therapeutic Drug Monitoring
Program, Multiple Assay".

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MS. CRONK: Q. Dr. Ellis, I ask you
briefly to turn to the back page of that exhibit, and
on the back there is a column. Well, first of all
there are various drugs listed on the left-hand side
of the page.

9

THE COMMISSIONER: Have you got that
yet?

10

11

MS. CRONK: I am sorry, Mr. Commissioner.

12

THE COMMISSIONER: It is all right,
carry on.

13

14

15

MS. CRONK: Q. There is an indication
on the back of the page, Dr. Ellis, of various drugs,
a listing of various drugs including digoxin?

16

A. Yes.

17

Q. And there is a category as well
indicating the therapeutic range for various drugs?

18

A. Correct.

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F-1

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DPeg

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Q. And as well there is an indication of optimal sample time for various drugs?

A. Yes.

Q. And a column as well for interacting drugs with the drug listed on the left-hand side of the page?

A. Yes.

Q. Could you read straight across with respect to the drug digoxin and tell me first what the indication is for optimal sample time?

A. Yes. This is the trough prior to the next dose. In other words, before giving the next dose you would take a sample.

Q. And there is no indication on that form as to how many hours prior to the last dose that sample should be taken?

A. No.

Q. In terms of the practice in your laboratory, would one have to have reference to the handbook in that regard to know the appropriate time prior to the last dose for the taking of the sample?

A. Not really, no.



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Q. So there is nothing in the face of this form that indicates when that sample should be taken save prior to the last dose?

A. Prior to --?

Q. The last dose?

A. The next dose.

Q. Right. And secondly, sir, what is the indication on the form beside digoxin for interacting drugs?

A. Quinidine.

Q. And, similarly, what is the indication of the therapeutic range beside the drug digoxin?

A. On this requisition it is 1.0 to 2.5 nanomoles per litre.

Q. That is a different form of measurement than we have heard about previously, Dr. Ellis. My understanding is that the system of measurement changed this year. Is that correct?

A. Yes, that is correct.

Q. Can you tell us when levels began to be measured in nanomoles per millilitre(sic) as opposed to nanograms?

A. April 4.



F-3

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2

Q. Of this year?

3

A. Yes.

4

Q. Perhaps it would be of

assistance --

5

THE COMMISSIONER: What are they

6

now measured in?

7

THE WITNESS: Nanomoles per litre.

8

N-A-N-O-M-O-L-E-S.

9

THE COMMISSIONER: What are

10

nanomoles?

11

THE WITNESS: A nanomole is ten to

12

the minus nine of a mole. It is a slightly
different way of expressing concentration.

13

THE COMMISSIONER: It is slightly

14

different. Would it be somewhat equivalent to
nanograms per millimetre?

15

16

THE WITNESS: There is a conversion

17

factor between the two. I believe if you take
the value in nanograms per ml --

18

THE COMMISSIONER: Is there a good

19

reason for having changed it from nanograms to
nanomoles?

20

21

THE WITNESS: To conform to an

22

international convention that is slowly moving

23

across the face of the world and has not quite got

24

25



F-4

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to the United States yet.

3

THE COMMISSIONER: I see. All right.

4

MS. CRONK: Q. Do I take it then,

5

Dr. Ellis, that up to and inclusive of the

6

beginning of April of this year the measurement

7

continued to be in nanograms per millilitre?

8

A. Yes.

9

Q. And starting in April of

10

this year it was switched to nanomoles per litre?

A. Right.

11

Q. And the therapeutic value in

12

nanomoles per litre as expressed on the back of

13

this form for digoxin is 1.0 to 2.5?

A. Yes.

14

Q. Can you in approximate terms

15

equate that for us to a nanogram measurement?

16

A. Approximately 2.0 nanomograms

17

per ml.

18

Q. Which end of it, the 2.5

19

nanomoles per litre - which end of it is the 2.0

20

nanograms?

A. The 2.5 nanomoles per litre.

21

Q. If I could ask you, sir, to

22

look briefly at the back of Exhibit 15B which is

23

the first requisition form introduced with the

24

25



F-5

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therapeutic drug monitoring programs --

3

A. Thank you.

4

Q. -- can you tell me, Dr.

5

Ellis, what therapeutic range is indicated on that
form for digoxin?

6

A. 2.0 micrograms per litre.

7

Q. For digoxin?

8

A. Yes. 0.8 to 2.0 micrograms

9

per litre.

10

THE COMMISSIONER: Where is that?

11

MS. CRONK: Sorry, sir, I think you
now have Exhibit 15C.

12

THE COMMISSIONER: All right, thank

13

you.

14

MS. CRONK: Q. And similarly, on

15

the original form, used in the therapeutic

16

drug monitoring program, what is the indication

17

of interacting drugs for the drug digoxin?

18

A. Quinidine is given.

19

Q. The same as on the revised
form?

20

A. Yes.

21

Q. What is the indication for

22

optimal sample time?

23

A. The trough prior to the next

24

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dose.

Q. And that is the same indication that is contained on the current form?

A. That is correct.

Q. Can you help us, Dr. Ellis, with respect to the therapeutic range indicated on the original requisition form? How does that relate to nanograms per millilitre, or can it be related?

A. On the original requisition?

Q. Yes. The 0.8 to 2.0.

A. Micrograms per litre. This is the same as nanograms per ml.

Q. So the range there is stated then to be 0.8 to 2.0?

A. Yes.

Q. Can you help me, Dr. Ellis, because that range is, in the context of the extract from the resident's handbook that we discussed this morning, a different range. Can you help me, or do you have any knowledge as to why a therapeutic range on a requisition form was stated to be at 0.8 to 2.0 range, when the therapeutic range indicated in the handbook is a different range?



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A. I think that the trough prior to the next dose in most patients of the hospital would probably be about 12 hours, so there is a slight difference in terms of when the blood is taken. One would expect the level to be slightly lower at 12 hours, compared with six to eight hours.

THE COMMISSIONER: Excuse me, I'm lost somewhere. Where is this reference that you are making to --

MS. CRONK: On the first requisition form, I'm not sure that you have it in front of you, sir, because I believe Dr. Ellis has it, the first one used in the therapeutic drug monitoring program, Exhibit 15B.

THE COMMISSIONER: Oh, I see, it is the difference between 15B and 15C. Is that right?

MS. CRONK: No, sir. It is the difference between 15B, 0.8 to 2.0 as a therapeutic range for digoxin and the therapeutic reference value set out in the Residents' Handbook which we referred to earlier.

Q. Do I take it then, Dr. Ellis, from what you have just said that, in your view, the indication for the optimal sample time contained in this form is an indication that the sample should



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be taken in the 12th hour before the new digoxin is administered?

A. There would be a period of time, yes, before the next dose, which would approximate 12 hours after the previous dose in many patients.

Q. That would compare or contrast with taking the sample six to eight hours after the last dose as is suggested in the Residents' Handbook?

A. There would be a difference there, yes.

Q. Would that account, if the sample was taken immediately prior to the administration of the next dose, would that account for the lower therapeutic range that is indicated on the back of this requisition form?

A. I think in part, yes, but also as I did qualify in the Residents' Handbook I think some authorities prefer a level of 2.0 as opposed 2.5 as being the level where perhaps toxicity starts to occur, and I think that perhaps those references were even more weight than the references that I had consulted earlier on.

Q. I see. But for your purposes,



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sir, during the July 1980 to March 1981 period you were talking about a maximum 2.5 nanograms per millilitre as being a satisfactory level. Is that correct?

A. With all the qualifiers, yes.

MS. CRONK: Thank you. I have no further questions of Dr. Ellis, Mr. Commissioner.

THE COMMISSIONER: All right, thank you, Ms. Cronk.

I guess the usual order - Mr. Bogart?

MR. BOGART: I understand that the hospital will be examining last on this one occasion, sir.

THE COMMISSIONER: Yes. I take it that is what you would prefer to do. All right.

CROSS-EXAMINATION BY MR. BOGART:

Q. Dr. Ellis, I would like to begin my questions of you, if I may, with a question concerning the RIA test. Last Thursday in chief you said that the RIA that you perform takes approximately two to two and a half hours. Have you got you right on that?

A. Yes.

Q. You said that the quantity of serum or plasma that one would need to perform the



F-10

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test is 50 microlitres?

3

A. 50, yes, for each tube.

4

Q. For each tube?

5

A. And the assay is only done in duplicate.

6

7

Q. Since you do it in duplicate you normally require a hundred microlitres?

8

A. Yes.

9

10

Q. Just one small question before we continue. At one point you said 50 microlitres and then you said 1/20th of one mml?

11

12

A. One ml, one millilitre.

13

Q. That is an equivalent measurement, I take it, is it?

14

A. Yes.

15

Q. To 50 microlitres?

16

A. I was just trying to give

17

some perspective.

18

19

Q. When we are talking about 50 microlitres, we are talking about serum, right?

20

What is the amount of whole blood that one requires in order to produce 50 microlitres of serum, or can you make that relationship?

21

22

A. Yes. This would depend on

23

the amount of red cells in the blood that was taken.

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You could approximately double that and that would be okay for many patients except for the very small infants?

Q. Yes.

A. So we're probably talking of 150 microlitres, thereabouts, to give yourself a certain amount of space between the serum and the red blood cells?

Q. Would the 150 microlitres of whole blood, would that then yield 50 microlitres or 100 microlitres?

A. It would yield, in most cases, 50 microlitres with a bit to spare.

Q. So if you wanted to do the RIA test once, and do it in duplicate, then do I understand that you would need 300 microlitres of whole blood?

A. Yes, at least.

Q. I'm just trying to get an idea of how much blood has to be drawn from the patient as opposed to the amount of serum that one requires to do these tests?

A. I believe we asked for .5 in the Residents' Handbook.

Q. I'm sorry, Doctor, I would not



F-12

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2 know, but if you want to check that --

3 A. If it is necessary to repeat
4 any of these tests obviously the occasion may have
5 gone if we have used all the plasma on the first
6 assay so we would ask for .5 mills of clotted blood
7 or plasma.

8 Q. I see, yes. It is here on
9 Exhibit 16. But that .5 millilitres of clotted
10 blood, is that the equivalent of 50 microlitres of
11 serum?

12 A. We are saying that if you
13 give us 0.5 mills then we can be reasonably
14 confident that you will get a result, even if we
15 have to do it several times.

16 Q. So that amount would allow
17 you to do the test in duplicate, and it would allow
18 you to do dilutions and that sort of thing as well?

19 A. Yes.

20 Q. Just moving on to dilutions,
21 though, if you get, as I understand it, if you get
22 a reading or if you got a reading over five in order
23 to find out exactly how many nanograms were present
24 in the blood, you had to then do a series of
25 dilutions and because you were expecting a finding
somewhere approximately outside the therapeutic



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range, if I can put it that way, the next dilution that you usually went to was two in one. Is that right?

A. Yes.

Q. How does that work in terms of the amount of blood and the amount of dilutant - rather, the amount of plasma and the amount of dilutant?

A. We would take equal volumes of plasma and dilutant.

Q. For the 2 in 1?

A. Yes.

Q. And for the 3 in 1, again you take equal amounts?

A. No, you take one volume of the patient's plasma and two volumes of a dilutant.

Q. I see. That is what I am trying to get at. When you do a 2 in 1 you use 50 microlitres of the patient's plasma but then you use twice as much dilutant. Have I got that right?

A. You may take 50 microlitres, you may take 100, depending on how much plasma you have.

Q. But you need at least 50 to do



F14

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the test, do you not?

3

A. To do the test, the final

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volume, yes.

5

Q. And if you want to do it in

6

duplicate, which you normally do, then you would
need 100 microlitres?

7

A. Yes.

8

Q. That would be the case whether

9

you were doing the so-called neat or you were doing

10

a dilution?

11

A. Yes.

12

Q. In other words, every time

13

you need to do one of these RIAs, whether it is

14

neat or dilution, you need 100 - if you want to do
it in duplicate - 100 microlitres of blood?

15

A. Yes.

16

Q. 100 microlitres of plasma,

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excuse me, which is approximately 300 microlitres

18

of whole blood?

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BMcra

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A. Depending on the amount of red cells, yes.

Q. So, it would vary. But that is a close approximation?

A. Yes.

Q. Okay.

Now then, just in terms of the dilution that you have told us about, you have told us that it takes you two to two and-a-half hours to do your RIA test. What about the dilutions? Does it take the same amount of time or is the time different between a neat RIA test and an RIA test done on a dilution?

A. This depends how you came to make the dilution. If you assay the sample and then you come to a result that is greater than 5 and then you have to start over again, then it is going to take longer. If somebody comes along --

Q. Excuse me. Longer than two to two and-a-half hours?

A. Well, you're going to have to repeat it again.

Q. Well, that's what I am trying to get at. If you have to repeat it again, do you have to go through all the same steps as the neat



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RIA test?

A. Yes.

Q. So, in other words, if you did them one after the other and you did a neat and then you did one to two dilutions, you would take about five hours?

A. Yes. Or you would conclude that the value was high as a result of the first test.

Q. Yes.

A. And then, perhaps the next day, you would analyze that sample on a dilution to confirm the value that you had obtained.

Q. Right. And that confirmatory dilution would take two to two and-a-half hours?

A. Yes.

Q. But, as I understand it, it is possible to do the dilutions consecutively, is it not?

A. Simultaneously, do you mean?

Q. I'm sorry, you're quite right, simultaneously.

A. Yes. If somebody comes along and says, we expect this value to be high; we're concerned about this patient, will you please assay it for us on a dilution as well as neat, then we



1
2 could do that.

3 Q. Yes.

4 A. And it would be just like
5 handling an extra sample.

6 Q. Yes.

7 So, assuming, for example, that there
8 was enough sample, somebody could come to you and
9 say, well, we think that we're going to be outside
10 the therapeutic range here; so do the neat, the 1 and
11 2 and the 1 and 5, for example, and you could do all
12 of those three tests simultaneously?

13 A. If there is indication to do
14 that, yes.

15 Q. Yes. All right.

16 A. I might also add that, if there
17 was indication to do that, then probably the dose
18 would have been withheld, the dose of digoxin would
19 have been withheld.

20 Q. At that point?

21 A. Yes.

22 Q. Yes. Well, that's because,
23 I suppose, people would be, because they are sus-
24 picious that the reading is going to be outside the
25 therapeutic range, they would have, at that point,
withheld -- given instruction to withhold the digoxin.



Ellis
cr.ex. (Bogart)

G4

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Is that the point you're making?

A. Yes.

Q. Yes.

A. But it also means the urgency with which you perform the test, whether it's two hours, three and-a-half or four or five, is not a major one, because the digoxin is being withheld.

Q. In the sense that the baby will no longer be given any more digoxin until you have learned the results of the test?

A. Yes.

Q. Okay.

Now then, you have told us about the standards that you used, and they were from Corning Medical, as I understand?

A. Yes.

Q. You told Miss Cronk that the Corning Medical standards, their highest standard that was supplied to you was 5.0 nanograms per ml.

A. Yes.

Q. Have I got that right?

A. Yes.

Q. But that, at some point, you adjusted the standard from 5.0 down to 4.7, 4.8.

A. Yes.



G5

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Q. Now, you said that you did that at some point during the period that was the focus of Miss Cronk's questioning of you; that is, July 1980 to March 1981.

A. Yes. My recollection is that that was the time when this was done.

Q. Yes. Can you just help me by being any more specific in terms of the time when these standards were adjusted during that period, July 1980 to March 1981?

A. Not without consulting the books that I think are in police hands, our record books.

Q. The record books?

A. Yes.

Q. Well, I assume that you are going to be back, Dr. Ellis.

A. Yes. I mean, is this a major concern of yours?

Q. Well, it might be.

A. Well, could you explain why and, then, I could perhaps give you an explanation.

Q. Well, why don't you tell me, in terms of my explaining, why you did it.

A. Why we did it?



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Q. Yes.

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A. Basically, because, as part of the quality control review, you analyze various quality control samples, as I indicated, and when we received a new lot number of standards from Corning Medical, we noted some change in the quality control values that we were obtaining.

8

Q. Yes.

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A. And this was confirmed by

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further quality control testing. After a period of time, when we were satisfied that this was what

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appeared to be happening, we elected to adopt slightly modified values, 4.7, 4.8, instead of 5.0, and a

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corresponding change to the other standards, too,

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in order to put our quality control values back to the mean value that they should be at.

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In other words, we assigned a value

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to the standards according to the quality control

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results that we were obtaining using them.

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Q. Did you assign different

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values to any of the other standards?

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A. To any of the other standards?

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Q. From Corning.

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A. You mean in terms of thyroxine, for example?

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Q. No, no. I'm sorry, we're talking only now about digoxin for the purposes of these questions.

For example, as I understand it, another standard would be .3.

A. 1.5.

Q. No, no. .5 is the one you adjusted.

A. 5.0 was the one we adjusted.

Q. I'm sorry, 5.0 was the one you adjusted. I'm sorry.

Did you adjust any of the other standards?

A. I believe the 2.5 was adjusted down to about 2.2.

Q. And this was over a period of time, by examining the standards, you felt that they ought to be adjusted from a value other than what was ascribed to them by Corning Medical?

A. Yes, for that particular lot number of standards.

You see, the basic thing is that Corning Medical standards are essentially designed to be used with Corning kits.

Q. Yes.



Ellis
cr.ex. (Bogart)

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A. So, there may be various matrix effects and various slight differences and subtle differences between kits. So that, when you take those standards and use them in an alternative system, you may, in fact, get a slight systematic error. For a number of years, we hadn't seen any of these problems but, when the lot number changed, we did start to notice them.

Q. Yes.

A. In fact, this was confirmed by subsequent lot numbers.

Q. Well, in terms of when you did it, doctor, can you tell me if you did it between December and March of 1981?

THE COMMISSIONER: December of 1980.

A. December of 1980.

MR. BOGART: Q. December of 1980 and March 1981.

A. Offhand, I can't say. I just don't remember.

Q. Yes.

A. As I say, it was when our Quality Control indicated we should do it; then we did it.

Q. Yes. Well, I would appreciate



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it, if it is possible for the next time around, if you could check your records so you would know when that was done, please.

A. Sure.

Q. Okay?

A. Sure.

Q. Thank you.

Now, when Mr. Cimbura was here - and I understand you were present for Mr. Cimbura's evidence?

A. Yes.

Q. And for cross-examination as well?

A. I believe so, yes.

Q. When Mr. Cimbura was here, he described in some detail the procedures that he used for his RIA test when he began his tests in 1981.

Now, as I understand from Mr. Cimbura, he used a kit from Beckman Company.

A. Yes.

Q. In contrast, you seem to have put your test together yourself using different components from different people. So that, for example, we heard on Thursday that you acquired the standards from Corning Medical, the controls from



1
2 Ortho Company, the radioactive digoxin from New
3 England Nuclear Company, the antibodies from Anti-
4 bodies Incorporated, California, and so on and so
5 forth.

6 Now, is there any reason why you
7 put your test together as opposed to acquiring a
8 commercially available kit?

9 A. I think I indicated that I
10 came to Toronto in 1976 and that this method had
11 been in use in 1975 and I think I indicated that it
12 had been evaluated and various kits had been looked
13 at it, I think in 1974, according to my information
14 from Dr. Cherian. So, we have to consider what
15 kits were available at that particular time.

16 Q. Yes.

17 A. Many of the kits, as far as I'm
18 aware, took quite a lot of serum sample.

19 Q. We're talking '74/'75 now?

20 A. Yes, that's right.

21 Q. Okay. Thank you.

22 A. So, there was the question of
23 sample volume, the question of what was in use around
24 the city, and I think that, essentially, our system
25 was in use at the Toronto General for a number of
years and we essentially adopted their method because



1
2 the Toronto General were really very satisfied with
3 the way that that method was working.

4 Q. When you say "method", this
5 amalgamation, as it were?

6 A. Yes, that's correct.

7 Q. That you told Miss Cronk about
8 on Thursday?

9 A. Yes.

10 Q. That came from Toronto General,
11 that is your understanding?

12 A. I think, essentially, that
13 particular method did come from the Toronto General,
14 that's right. They had had a number of satisfactory
15 years with that.

16 Q. All right. So, that's in
17 '74/'75?

18 A. Yes.

19 Q. Subsequent to this, did you,
20 yourself, make any evaluation of the commercially
21 available kits?

22 A. Yes. We were getting quite a
23 number of kits from Corning Medical at around 1978/
24 1979.

25 Q. Well, just so I understand
this, I take it Corning Medical has a kit as well?



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A. A complete kit, yes.

Q. Okay.

A. And it seemed reasonable at that particular time to evaluate their kit because this would assist us with purchasing, we would just order several kits from that company and it would be easy to do that. So, we did look at that particular kit at that time.

We also looked at a clinical assays kit. Actually, what happened was that we had to modify the Corning kit because it required too much sample.

Q. Can you just remember how much sample?

A. I think it was about 200 micro-litres of serum was recommended for a single tube.

Q. For a single tube?

A. Yes.

Q. So, in other words, if you wanted to do it in duplicate, you need 400 microlitres?

A. I think that was the position.

Q. So, that requires about 100 microlitres more than your RIA?

A. Yes.

Q. Or the test that you performed?



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A. 100 microlitres more?

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Q. Well, I thought you said

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that you needed 300 microlitres of whole blood to
do the test in duplicate.

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A. Didn't I say 200 microlitres
for each single tube for Corning?

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Q. Yes, for Corning, yes.

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A. That's right, which is 400
microliters of serum.

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Q. Yes, that's right.

11

A. Okay.

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Q. Okay.

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A. So, we're talking about a mil
or just over a mil of blood.

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Q. Right. All I'm saying is
that that was more and, as I understand from what
you have told me earlier, that was 100 microlitres
more than what would be required using your RIA test.

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A. No. It's 150 microliters per
tube more, isn't it, which makes it 300 microlitres
more, doesn't it? It requires more serum, okay.

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Q. Okay. I'm sorry. I thought
you were talking whole blood. Are we talking serum?

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A. Well, I was talking serum.

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Q. Okay. I'm sorry.

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A. Okay. So, more serum, or more blood, was required. We elected, in fact, to go over to Corning Medical at that particular stage because we modified it to use, I think, 50 microliters. The only problem was when we introduced it; the assay did not perform as well as we had expected in routine use. So, we moved back to our mixed method, if you like.

Q. Yes.

A. I believe also that Dr. Soldin has evaluated the clinical assays kit, again, a subsequent one, a few years later, and also a kit from Serono Diagnostics, S-e-r-o-n-o. I don't know of any others that he has evaluated. Well, of course, he's evaluated the Abbott TDX system, and he will be discussing that with you later.

Q. Yes.

A. So that this method has been compared with a number of others.

Q. Did you ever compare it with Beckman?

A. No, we didn't, no.

Q. I see.

Now, I realize that, on Thursday, you said you had no experience running RIA assays for



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1 digoxin with Beckman, using the Beckman kit. You
2 have just told me now that neither you nor anyone
3 else of whom you are aware ever tested the Beckman
4 kit. But bearing that in mind, I would like to
5 ask you some questions about the apparent difference
6 between the length of time it takes to do your RIA
7 assay and the length of time that it takes Mr. Cimbura
8 to run his Beckman test.

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His evidence, as I understood it, was that it takes from a day and a half to two days to run his RIA test for serum. His evidence was also that it takes longer for tissue, but let's ignore that difference, because as I understand it you only did RIA on tissue a couple of times, and as I understood you on Thursday to say it was with quite equivocal results, so you never did much RIA on tissue. So let us just talk serum.

THE COMMISSIONER: I wonder if I could interrupt now, I think we might take a break. This, once again, I don't know that while it might be of importance the fact that one procedure takes longer than another, I don't know. This again, Dr. Ellis, I don't know if you want to discuss this privately with Mr. Bogart? These are the matters that I would hope that with sort of prior discussion you could get out of the way. Unless it is a matter of importance I don't see the importance yet, but there may be an importance.

MR. BOGART: Well I am simply intending to ask the witness whether ---

THE COMMISSIONER: I know what you intend to ask him. All I am really asking you is why you are asking him what is the vital importance



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of whether it takes a longer or a short time.

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MR. BOGART: Because it may become
important with respect to individual cases, sir.

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THE COMMISSIONER: Yes, all right.
I will have to leave it with you, because I just
ask you to bear that in mind. Perhaps at the
break perhaps you could pursue it directly with
him.

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MR. SCOTT: I think I was away
playing tennis at the time that counsel met with
Dr. Ellis for an hour and a half.

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THE COMMISSIONER: They met before
he started giving his evidence which isn't of
course such a good time. It is better after he has
given some evidence and my hope was that some of
these questions, and I don't want to be rude, but
some of them which I would describe as Examination
for Discovery questions we could get out of the
way.

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MR. SCOTT: I am surprised at the
description, would it be useful going on if the
future meeting were to take place after the
examination in-chief?

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THE COMMISSIONER: It would be very
useful, that is the time I would like it to take



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place. Would it be a good idea to have that meeting perhaps now? I know we have had one already, and I really don't know. If it would shorten things up I would be all for it.

MR. BOGART: Well, I am ---

THE COMMISSIONER: How long did you intend to pursue this?

MR. BOGART: Sir, I would like to ask him one question about it and then I will move to another area.

THE COMMISSIONER: You prefaced your question with "I'm going to ask you a series of questions" and that triggered a certain alarm in me.

MR. BOGART: Well if I said series, sir, I misspoke myself.

MR. SCOTT: If it is only one question that seems to be a gamble we should promptly take.

THE COMMISSIONER: Let us try it out.

MR. BOGART: If I had asked the question and he had given the answer we probably would have avoided a discussion.

THE WITNESS: I was asked this question at our informal meeting, I don't know



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2 whether you were present at that?

3 MR.BOGART: Q. I would just like
4 you to say on the record whether you can assist us
5 about the discrepancies in the times for the tests.
6 Now, if you can't, all you can say is no. If you
7 can, I would just like you to say what it is.

8 THE COMMISSIONER: All right, can
9 you help us?

10 THE WITNESS: Okay. Well, there
11 may well be some explanations as to why the
12 procedure takes longer.

13 Firstly even with serum I understand
14 on some occasions the Forensic Science laboratory
15 does extract the serum, especially from postmortem
16 samples.

17 Secondly with respect to measuring
18 the radioactivity of the samples later on, as I
19 indicated at that meeting we have a machine which
20 will measure 12 samples simultaneously. So that
21 means in two minutes you get 12 answers. It may
22 perhaps be that Mr. Cimbura has a machine which
23 will only measure one sample simultaneously at a
24 time, and so this will extend the time needed to
25 measure the radioactivity. It may depend also
on the size of batches that he does and on the



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actual counting time involved. So there are technical reasons why it might well take longer.

Q. Could that potentially extend the time up to a day and a half to two days?

A. If there is no hurry for the results it may be best to put them on the gamma counter overnight and come back the next day and look at those results.

Q. All right, I will take the matter up further with Mr. Cimbura.

THE COMMISSIONER: Now we will take our break for 15 minutes.

--- Short Recess at 10:35 a.m.

--- Upon Resuming at 10:50 a.m.

THE COMMISSIONER: Mr. Bogart?

MR. BOGART: Thank you Mr. Commissioner.

Q. Dr. Ellis, in-chief, Ms. Cronk, last Thursday, asked you whether the manufacturer of the antibody, which as I understand it is Antibody Inc., tested for certain drugs, and I believe I have got this right that she asked you about Quinidine, propranolol and furosimide. Are



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you with me?

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A. Yes.

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Q. And my understanding is that
your answer was you didn't know.

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A. Whether the manufacturer had
tested those individual drugs?

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Q. Yes.

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A. That is correct, yes.

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Q. I would just like to ask you
about some other drugs. Can you tell me whether
or not, to your knowledge, the manufacturer tested
for them. Lanatoside ---

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A. Can I just clarify one issue?

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Q. Yes.

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A. There are two different kinds
of interference from what I understand. One
interference is the analytical interference in the
assay with substances that are similar to digoxin,
perhaps, if we use that expression.

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Q. Yes?

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A. The other interference is a
kind of physiological interference which results
in an increased digoxin level which is really a
true digoxin level. In other words you may give
a patient a drug and that patient as a result of



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that drug administration, which is not digoxin,
the digoxin metabolism may be impaired and the
digoxin level, the true digoxin level may rise.

Q. Yes.

A. And so I think there are two
different groups of drugs and you seem to have mixed
those two groups of drugs together.

Q. No, I was - as I understood
it Ms. Cronk asked you about those three drugs and
whether the manufacturer tested for them or not.

A. Yes.

Q. And your answer was you
don't know.

A. Correct, but he would not be
able to test for them because their effect is on
the body and it's handling of true digoxin. It is
not an in vitro effect whereby you add the drug to
the test tube and you test for it.

Q. So in other words what you
are saying is not only did he not test, but he
couldn't have tested for them?

A. There would have been no
indication for him to test a number of the substances
you mention.

Q. Well I mentioned quinidine,
propranolol and furosimide?



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A. Yes.

Q. How about lanatoside C?

A. I don't have any information
as to whether he tested for those or not.

Q. Deslinocide?

A. No. I have no information on
that either.

Q. Digoxigenin, please help me
with the pronunciation.

A. Yes, I have no information
on that.

Q. Acetyl-digoxin?

A. I don't even know whether
that was (a) available; or (b) had been marketed in
1972, 1974 when these things were being tested.

Q. You are referring to the last
named drug that I mentioned?

A. Acetyl-digoxin, yes, I don't
know if it is in use in Ontario right now, is it?

Q. I'm sorry I'm not able to
help you with that. I am just asking you whether
you know whether the manufacturer tested for these
drugs.

As I understand Mr. Cimbura's evidence
the drugs that I have just named are substances which



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are chemically similar to digoxin?

A. Some of the substances you just mentioned are, yes.

Q. And so far as you know the manufacturer did not test for these drugs?

A. He has given no indication of that.

Q. Thank you. Now then, Ms. Cronk continued to ask you about the RIA, asked you about several known factors with respect to the RIA tests you were running and with which you agreed in terms of their effects of the RIA.

The first one was that the RIA test was intended to encourage reactivity of the digoxin to the antibody you were using?

A. I am sorry, could you repeat that?

Q. Well perhaps if you have got a transcript it may assist you.

A. Well, could you just read the sentence you are referring to?

Q. Sure. Yes, the first one was:
" ... it was intended to encourage the reactivity of digoxin to the antibody that you were using..."



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THE COMMISSIONER: Excuse me, you
are reading from what page?

MR. BOGART: Well in fact I am ---

THE COMMISSIONER: All right, have
you got it?

MR. BOGART: Page 938-939 Your
Lordship.

THE COMMISSIONER: 930?

MR. BOGART: 938.

Q. This is a precis of what you
were asked and I'm trying to speed this up, if
there's any qualifications you want to make, please
do.

A. What was your question again,
I am sorry.

Q. I'm just suggesting to you
she put that factor to you and you agreed with it?

A. In the context that she put
it to me?

Q. Yes, that's right.
Page 938, sir, the bottom of the
page, line 17.

A. I am sorry, I have got it,
yes.

Q. She put that to you and your



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answer was "Yes"?

A. Yes.

Q. I'm sorry, are you with me,
Dr. Ellis?

A. Yes.

Q. So she put that first factor
to you and your answer was "Yes"?

A. Yes.

Q. And then secondly she said:
"...you were aware that digoxin
by-products or metabolites might be
produced which were of the kind which
would react similarly, like digoxin,
to the anitbody?"

Agreed?

A. Yes.

Q. And then the third element
was:

"...as you are aware that could
react to your antibody were the
drugs prescribed by the supplier of
the antibody and you had information
available to you from that supplier
as to the likely degree of cross
reactivity you might suspect from



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those listed drugs."

A. Yes.

Q. And then the fourth factor was that you had become aware in this Courtroom of the substance X, that is Dr. Seccombe's evidence.

THE COMMISSIONER: Yes, I think Dr. Ellis ---

THE WITNESS: Was that a question?

MR. BOGART: Q. Yes, I'm sorry, sir, I just wish to refer him to his evidence. As I understand it Ms. Cronk then asked you, given those factors, and this is on page 40, were you so sure that what you were measuring at any time was pure digoxin?

A. We were sure that anything we were measuring at any given time was digoxin?

Q. Pure digoxin, page 940. It is your answer to the question that I want to ask you questions about.

A. I see.

THE COMMISSIONER: The question is how was he so sure? How was he sure?

MR. BOGART: Yes. The answer he gave ---

THE COMMISSIONER: What is the



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question, I am lost?

MR. BOGART: Q. Sir, can I just state what the answer is that he gave on page 940, he said:

"Simply because I believe that the majority of the reading that we produce is digoxin."

This is particularly in the case of:

"....children over six months of age."
Page 940.

A. Yes.

Q. Now so I understand it, with children over six months of age it is your position that you could be confident that the majority of the reading was made up of digoxin?

A. That would be my assertion on the basis -- do you wish me to go through that, is that what you are asking me?

Q. Yes.

A. Basically an animal was injected with a derivative of digoxin some years ago and it produced certain antibodies that bound digoxin, the manufacturer assures me, with high specificity. That anti-serum and that antibody and that method has been used since 1975 onwards.



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Independent quality control assessment has been made of that assay and we have had no reason to believe that what we and other people have been reporting as digoxin is anything other than digoxin. With the limitations that any radioimmunoassay has in that we would report thyroxin, for example, as a hormone measured by the thyroid gland and we would recognize that certain other constituents of the blood plasma might contribute to that thyroxin reading. Digoxin was no different from that in our view at that time.

Q. And that answer is in respect of children over six months of age. What about children under six months of age?

A. In respect of children under six months of age, specifically under two months of age, I think we have to view these results with caution in the light of the information given by Dr. Seccombe and others, and also found by ourselves at the Hospital.



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/DP/ak

Q. Pardon me?

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A. In the light of observations

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that we had made in the hospital ourselves.

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Q. And what are those observations?

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A. These are the ones that I

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indicated.

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Q. On Thursday, the one about

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if you monitored the child --

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A. Who has not been treated -

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several children who were not being treated with

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digoxin in 1982 on Ward 7F and values I think as

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high as 1.3 were obtained in one child. The majority

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were under .5. There were one or two at .6 or .8

or thereabouts.

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Q. Yes.

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A. So that kind of ties in in

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retrospect with these other observations that other

people have made.

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Q. I believe also you mentioned

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something about the clinical symptoms of the children,

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that there are instances where you reported higher

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readings to the floor of digoxin and they were not

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particularly disturbed by that simply because they

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were monitoring the child very closely.

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A. Yes.

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Q. So that in those instances it would be the clinical symptoms of the child that would be viewed, in substance, more important than the actual digoxin readings that you have found.

A. They would have to make a decision as to whether they took the digoxin reading totally as it appeared. Perhaps they would lower the values and it might in fact prove that the child's clinical condition deteriorated so they had to raise the amount of digoxin again a little.

Q. At page 941, you are really amplifying your response to Miss Cronk, and at line 15, you say:

"So I think we have some kind of, admittedly a little bit tenuous, indication that for clinical purposes furosemide -- "

We are talking here about furosemide. "...and all the other drugs used in the hospital don't have a major significant effect on the result that we produce. I think that is shown in the literature as well."

Can you just tell me what literature you are referring to?



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A. You mean specifically?

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Q. Yes, if you can recollect

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specific articles?

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A. I cannot recollect specific

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ones just off the cuff but I can obtain those if
you want them.

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Q. If you have them, I think that

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might be very useful.

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THE COMMISSIONER: That is sort of

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a large order, is it not?

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MR. BOGART: Except that the only

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thing, sir, is, this is the basis of his response

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that furosemide --

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THE COMMISSIONER: I understand

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that.

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MR. BOGART: So I would think that

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it would be appropriate to be able to inquire into

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the basis for his conclusion, and the basis for his
conclusion --

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THE COMMISSIONER: The basis for

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his conclusion, I think, is his experience.

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MR. BOGART: But that is not what

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he said, sir.

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THE COMMISSIONER: All right, sorry.

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Yes, Mr. Scott?

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MR. SCOTT: Perhaps we could provide him with the notes of where the literature could be found. Would that be easier, Doctor?

THE COMMISSIONER: I would think perhaps a reference to all of the literature, but I really think a specific question would be better than please give me the whole basis of your information on this. That is an impossible to answer. If anyone were to present it to me, I could not answer it.

MR. BOGART: I appreciate that, and I would be sympathetic if that were the question, but that is not the question.

THE COMMISSIONER: All right.

MR. BOGART: The question I am asking him is what is in the literature that led him to believe that there is a minimal cross-reaction between furosemide and any other --

THE COMMISSIONER: It is not just the literature, it is his experience and that is what he is making quite clear. It is his experience and the experience of the hospital and the experience that they have had with the test, that he is of the belief that it is the majority, particularly with children over two months, is digoxin.



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MR. BOGART: Over six months, I think was his answer.

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THE COMMISSIONER: He said over six months but he has now said over two months. Now, what is your question? You want to know what studies he has made, what he has --

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MR. BOGART: No, sir. On Thursday, he referred ---

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THE COMMISSIONER: I have the reference here. He said it is also in the literature.

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MR. BOGART: Yes.

THE COMMISSIONER: If you were to say my understanding of the law of contracts is X and then I were to ask you and what, pray, is your study of the law of contracts, you would have some trouble, would you not, to tell me just what books you read.

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MR. BOGART: I might, off the top of my head. If on the other hand, sir, you were asking me about the doctrine of consideration, I might be able to give you some references fairly quickly. If he cannot give me references, that is all you have to do is say no.

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THE COMMISSIONER: All right. I'm not, obviously, persuading you of anything.



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MR. BOGART: And, sir, I do not wish to take up your time unnecessarily. If you are saying to me that I cannot ask this question --

THE COMMISSIONER: I am not saying that you may not ask the question. All I'm doing is trying to get you to be a little bit more specific.

However, Dr. Ellis, what can you do to help us out of this quandry?

THE WITNESS: I can supply some literature. Do you have reason to believe that furosemide interferes with our assay at the Hosptial for Sick Children?

MR. BOGART: Yes, I may have reason to believe that.

THE COMMISSIONER: If you have that reason, put it to him, because then he can deal with any specific question.

If you can say, on page so and so of such and such a document it is stated that furosemide or some other substance will interfere with readings of digoxin, put it to him, by all means, because that is a question that he can answer.

MR. BOGART: Sir, I do not come



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here equipped with a battery of experts. I'm not going to give a speech about this but this point has come up again and again. There are several of us here without batteries of experts and all we can do, at least one of the main things that we can do, is test the witness.

THE COMMISSIONER: I do not want you to get paranoid about this, Mr. Bogart, I really don't. I am trying to get you to do what would be most constructive for your own interest.

MR. BOGART: Thank you, sir.

THE COMMISSIONER: Because you won't impress me if you simply say to every witness, please tell me all the books that you have studied in order to reach this conclusion, because I will pay no attention to that kind of question. But when you start saying to him something that indicates that perhaps there is something wrong with what he is saying, then I will pay a great deal of attention to it.

I am merely giving you, and I hope I am not being too patronizing, a lesson in advocacy. That is the way you get a judge to pay some attention, give him some facts, something specific that he can hang onto.



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MR. BOGART: Well, sir, I thought
we were here dealing at the general level --

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THE COMMISSIONER: Well, I did not
think that we were doing it at the general level.
I was hoping that we were going to get specific
because that is the way my mind, for what it is
worth, functions.

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MR. BOGART: I am sorry, sir.

THE COMMISSIONER: I do not intend
to write a competitive analysis of digoxin, and how
you go about various tests. I do not intend to
do that. I intend to evaluate what has been done
to determine whether it did or did not produce
readings that showed a toxic level either before
or after death in the children.

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Now, I would have thought that was
obvious. That is what my intention is, to find
that out. If the system that they used was no good,
I want to hear about it; if the system was good, I
want to hear about it; even if the system was
mediocre, I want to hear about it; but I do not want
to have to devise a system of my own that will
be better, because I cannot do it.

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MR. BOGART: Sir, I appreciate
that. It is obvious that this question is not, in



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your judgment, an appropriate one. I think we should
just move on.

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THE COMMISSIONER: All right.

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THE WITNESS: Could you perhaps
give me the specific reference to your belief that
furosemide interferes with our assay?

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MR. BOGART: The specific reference
is this is a drug that has been mentioned several
times in the hearing already, and I would just like
to know what the basis of it is. That was my
original question, but we have now consumed 10 minutes,
so let us just move on.

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Q. Dr. Ellis, during the period
under discussion, July 1980 to March 1981, can you
tell us, did you ever take any of the tests you did
to any other place, excluding the Forensic Centre,
for testing or retesting?

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A. Did I ever take?

Q. Yes, or anyone on your behalf?

A. I believe in the preliminary
trial evidence I indicated that one sample had been
sent to Mount Sinai Hospital, and I'm aware of that
sample.

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Q. And I believe during the
Preliminary Inquiry, and the reference is your



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evidence, Volume 12, you said you did that because on some occasions, and I am quoting here, these are your words --

MR. SCOTT: Page, please?

MR. BOGART: Page 20, Mr. Scott.

Q. "...radioimmunoassays are subject to very unusual interferences and these happen on very, very rare occasions with some samples. We have not had experience with digoxin but with some analysis you can get a completely different answer by assaying the sample using a different antibody and a different technique."

I take it that that was the reason why you did send out the one sample to Mount Sinai?

A. Yes.

Q. Because it was your suspicion, although you did not know, that it might be that if you re-assayed the sample, using a different technique, you might get a different reading.

A. We might get confirmation that it is high or we might get a totally normal answer.

Q. That is right. You might get confirmation of your result or you might get a



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different reading.

A. That is not quite what I said,
but I take your point.

Q. By using a different technique.

A. Yes.

Q. That was the point of sending
out the sample, to subject it to a different technique.

A. Yes, and a different radioimmuno-
assay, a different antibody and a different separation
technique.

Q. Thank you very much.

Then I just have one more area to
question him on, sir, and that also concerns some
of the evidence that you gave at the Preliminary
Inquiry, Dr. Ellis. It relates to Miss Cronk's
questioning you on tests for digoxin that were done
from March 1981 to January of 1982.

As I understand it, your response
to her on Thursday was that in March of 1981 there
was what the Commissioner called a blanket examination
of all children, at least the children in Wards 4A
and 4B, for digoxin.

A. For a short time, yes.

MR. SCOTT: What page, please?

MR. BOGART: The page, Mr. Scott,



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is 915 of Dr. Ellis' examination-in-chief and I am
quoting the Commissioner.

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Q. So that was the first series
of tests, am I right?

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A. The first series of tests?

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Q. Yes, there were two tests that
you told Miss Cronk about.

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A. Two series of tests?

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Q. Yes.

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A. Where children who had not been
prescribed digoxin were tested?

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Q. Yes, that is my understanding.
The first was in March 1981.

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A. I believe that to be the case,
yes.

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Q. Well that is the answer you
gave on Thursday.

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A. I cannot remember any previous
occasions that would have been done.

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Q. Thank you, sir. Then the
second occasion was January 1982.

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A. Yes.

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Q. That is the business on Ward 7F
where there was indication of children who were not
prescribed digoxin had nevertheless somewhat higher

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readings of digoxin in their system. There is at least one instance where it was over one.

A. Yes, there were some very sick children who were being screened for a number of possible problems, including possible digoxin administration.

Q. Thank you, sir.

The difficulty I'm having with this, Dr. Ellis, is, as your evidence on Thursday relates to the evidence that you gave on the Preliminary Inquiry, because my understanding from reading the Preliminary Inquiry, Volume 13, is that - this begins on page 17, is that in fact there were two series of tests done that ran from March 1981 to February 1982.



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MR. SCOTT: Where is this, please?

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MR. BOGART: Mr. Scott, beginning

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on page 17, Volume 13.

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A. Not run from, on two separate

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occasions, March 1981 and January 1982.

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MR. BOGART: Q. Well, that's the

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difficulty I'm having, Dr. Ellis, because if you

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look at your evidence in Volume 13, beginning at

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page 17, and you look at the dates, the dates run

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from March to February.

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MR. SCOTT: Could he just have a moment

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to read it, Mr. Commissioner?

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MR. BOGART: Of course.

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MR. SCOTT: I think beginning here.

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Does that take you back?

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THE WITNESS: Yes, I think so.

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You're talking about autopsy digoxin.

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I wasn't.

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MR. BOGART: Q. Well, as I under-

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stand it, there are two categories of tests; one is

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autopsy readings and one is non-autopsy readings.

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Basically, all I want to ask you,

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Dr. Ellis, is, first of all, whether in fact the

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evidence that you gave, that I have understood the

evidence that you gave in the preliminary inquiry



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correctly; that, in fact, there were tests continuing from March 1981 through to February 1982.

A. On autopsy samples.

Q. Well, and non-autopsy samples.

A. This came up in relation to the lower limit of detection on the assay. I indicated that, in most instances, patients who were being treated with digoxin would be the only ones that we would assay for digoxin in their plasma. I indicated that there were two instances on living, healthy patients where blood samples had been taken even though it was known that the patients had not been treated with digoxin. Those two occasions were in March of 1981 and January of 1982. In the meantime, there was an ongoing study of autopsy samples that were being taken as part of the police work. So, this is additional, but these were autopsy samples as far as I'm aware, in the majority of cases anyway.

Q. Well, can I just refer you to page 17 of your evidence --

A. Right.

Q. -- line 20, where the question is.

"These are not autopsy readings you are giving us now?"



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"A. No, as far as one can see,
these samples have not originated in
Pathology."

And then you list twelve instances where there are
readings in excess of 5.

A. But those are patients who
were well being treated with digoxin. What's the
problem?

Q. Well, look on page 19, Dr.
Ellis, page 19, line 20.

"Q. Just before we go on, could
you indicate whether the baby was on
digoxin, Baby Stone."

"A. I have no record in our book
as to whether these children were on
digoxin or not."

A. If I could add in parentheses,
but I would assume that these children would be on
digoxin because a digoxin level had been measured,
and this was the usual practice.

Q. Well, yes, I know, but that's
what I would like to get clear.

A. Well, I did say I have no
record in our book. I did say that the children were
not -- I have no record as to who treats the children



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with digoxin or what the dosage is in our laboratory books.

Q. Well, the thing is -- So, the answer that you can give me today is the answer that you gave at the preliminary inquiry; you simply don't have a record?

A. Well, that's what I said, yes.

Q. So, you don't know whether these children were on digoxin or not?

A. I feel that that came out quite clearly at the preliminary inquiry.

Q. Yes. All right.

Can you - and you don't have to do it today but, before you come back - review your evidence, Volume 13, from pages 17 to 35.

THE COMMISSIONER: What is it there that specifically you want him to review?

MR. BOGART: Sir, all I want him to do is review his evidence from pages 17 to 35 and ask him if, when he returns, there is anything in terms of his evidence which he wishes to qualify or amend.

THE COMMISSIONER: Well, could you point to some specific point that you want him to qualify or amend that you think is wrong? That's



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what's wrong with this line of examination. "Would you please go through all of your evidence and tell me if you want to change it" isn't really that helpful. You can ask that kind of question; he can do it, and I may say, if his answer is, no, and there should have been something he should have changed, I would pay absolutely no attention to it because you can't trap a man that way; you've got to point to what the particular feature is that you want to have clarified and ask him about it.

MR. BOGART: Well, sir, actually, I'm doing this because I thought this was going to shorten it up.

Dr. Ellis, at the preliminary inquiry, gave evidence about babies from March 1981 --

THE COMMISSIONER: Could we not just ask him now if, in fact, it was so; if, in fact -- I understand he has assumed that all of these children were prescribed digoxin.

MR. BOGART: Well, no, I think he said that he --

THE COMMISSIONER: All the ante mortem tests were on children who were, except in these special examples that he has given.

Now, if you have something to suggest



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that that is not so, could you not put that question to him?

MR. BOGART: Sir, I have nothing to suggest that except what is in the transcript.

THE COMMISSIONER: Yes. All right.

MR. BOGART: And that is, he has no record of it.

THE COMMISSIONER: All right.

MR. BOGART: Now, if he has anything different to add to that, I'm giving him an opportunity to do so.

MR. SCOTT: Well, there is one other matter. This examination was stated to be an examination of the general testing methods --

THE COMMISSIONER: Yes.

MR. SCOTT: -- the manner in the Hospital, and my friend is now going right to another aspect of the case. Would it be appropriate to leave the matter over until, if it ever happens, Dr. Ellis is recalled to give evidence, and I will remind him to read pages 13 through 17 before he comes again --

THE COMMISSIONER: Yes. All right.

MR. SCOTT: -- under my stern tutelage?

THE COMMISSIONER: All right. Well,



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perhaps I should depend on you. The real problem is, if we leave too much over, we will end up, of course, having just as much cross-examination on this issue - this is the one issue we are to have - as we've already had. That is what I'm worried about.

MR. BOGART: Well, sir --

THE COMMISSIONER: Just a moment.

Yes, Miss Cronk.

MISS CRONK: I'm sorry, Mr. Bogart.

Mr. Commissioner, this may be of some assistance and it may not but, in the hope that it will be, because of the evidence that Dr. Ellis gave in chief last week concerning tests that were conducted on children who were known not to have received digoxin, that is a matter which I understood Dr. Ellis' evidence, those tests were conducted by Dr. Soldin. Dr. Soldin will be here, I hope today, to commence his evidence in chief and, on that aspect of it - ante mortem sampling - that can be pursued through Dr. Soldin.

It is also the intention of Commission Counsel to call either Dr. Soldin or the appropriate individual from the Hospital at a later date to talk about autopsy and post mortem testing results as particular to the investigation, the time



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period that we're looking at. So, in that context, there will be further evidence.

THE COMMISSIONER: That will solve the January 1982 problem. It doesn't solve the March problem.

MR. BOGART: Well, it may, sir, in this sense: Dr. Ellis, on his preliminary inquiry, said that he was reading from a summary.

Q. As I understand it, Dr. Ellis, you didn't do these tests?

A. In March 1981?

Q. From March 1981 to February 1982.

A. But I have indicated they are two distinct occasions; one in March and one in January.

Q. But this is the problem I'm having: If you look at the dates, sir, there are dates which extend throughout the year.

A. Okay.

Q. You know, that's the problem I'm having.

MR. SCOTT: Let him answer. He's going to tell you.

MR. BOGART: Okay. I'm sorry.



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A. I think, at the preliminary inquiry, I was asked by either the Judge or the Defence Counsel to report on any abnormal digoxin that we had come across in the course of our routine analysis for digoxin at the Hospital for Sick Children in the timeframe that you are discussing.

Q. Yes.

A. I believe I protested on that occasion that, by abnormal, what level should I take, and I think that some arbitrary decision as to 5 nangograms per ml was regarded as appropriate.

As a result of that, on the evening of the - would it be the Tuesday or the Monday when I gave evidence at court, I went through one and-a-half digoxin notebooks looking for values greater than 5.

Q. Yes.

A. And I reported these to the preliminary inquiry.

As I quite clearly stated, I have no record of those in our book as to whether these children were on digoxin or not.

Now, do you have some indication that I had a record in our book that they were or they weren't?

Q. No, sir, I don't.



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A. Okay.

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Q. That's why I'm asking you

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whether you have anything to add to your testimony

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and, moreover, if this is not an appropriate time

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to ask questions about these particular tests, or I

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should ask them of Dr. Soldin or anyone else, I'm

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content with that as well.

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All I am saying is that you gave this

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evidence; we have it. Some of us may want to refer

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to it, and I just want to give you an opportunity

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to modify it or correct it in any way you wish to.

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You don't have to do it now. You can do it subse-

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quently.

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THE COMMISSIONER: Well, I think

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whatever he will do, he will do with the advice of

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counsel.

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So, if all of these assurances you've

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got are enough to move you on to the next subject,

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I would be happy.

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MR. BOGART: Sir, it's not only

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enough to move me on to another subject; it's enough

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to make me stop. Thank you.

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THE COMMISSIONER: Very well. Thank

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you.

Now, Mr. Strathy, we are going to



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1 rise at 12:45. Do you want to --

2 I'm sorry, are you next?

3 MS. SYMES: Mr. Commissioner, I
4 was going to ask, sir, if I could be heard next and
5 I could complete my quesitoning by 12:45.

6 THE COMMISSIONER: Yes. All right.
7 If you don't finish by 12:45, then you will be
8 speaking to an empty courtroom because we are
9 rising at 12:45!

10 MS. SYMES: Mr. Commissioner, I will
11 speak very briefly.

12 THE COMMISSIONER: Has anybody got
13 an objection to this? I take it you are agreeable?

14 MR. STRATHY: That's fine with me.

15 THE COMMISSIONER: All right.

16 CROSS-EXAMINATION BY MS. SYMES:

17 Q. Dr. Ellis, you have told us
18 and Mr. Bogart today that the Hospital for Sick
19 Children had essentially made its own kit and, in
20 fact, I gather that the results from the Hospital for
21 Sick Children kit for digoxin is as good or better
22 as the kits available commercially?

23 A. I believe that to be the case.

24 Q. And specifically, in comparison
25 to, say, the Beckman kit, would you expect that there
would be any differences in the results you get from



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the Hospital for Sick Children kit and the Beckman kit?

A. I would have expected there to be slight differences, yes.

Q. Would those differences be significant?

A. What do you mean by "significant"?

Q. Well, first of all, on a therapeutic level, if you had done exactly the same test on a sample of blood using the Hospital for Sick Children kit and on the Beckman kit, would you expect one to say "give no more digoxin" and the other to say "more digoxin is appropriate"?

A. There is always a certain amount of analytical error in any measurement. When you start to compare different measurements, different kits, then the range can become quite wide, depending on the quality of the kit. I have no experience of the Beckman kit.

Q. In terms of the Hospital for Sick Children kit, what is the standard deviation?

A. For what period are you concerned?

Q. Well, let's take the time in



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question, which is July 1980 to March 1981.

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A. What level of digoxin do you

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want me to --

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Q. Let's take within the thera-

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peutic range.

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A. In the therapeutic range,

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Ortho Quality Control A, July.

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Q. That's fine.

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A. The claimed value with the

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qualifiers to that was 1.0. We obtained average

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results over a period of 30 days of 1.13. Two

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standard deviations were 0.28; in other words, one
standard deviation is 0.14.

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THE COMMISSIONER: I'm afraid I don't

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understand that. This is a deviation between what
and what?

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MS. SYMES: Q. That then is, you

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would expect that 95 per cent of the sample would

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be 'X'; that is, the mean minus 2 standard deviations

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to the mean plus 2 standard deviations; is that

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correct?

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A. We would expect, if you gave

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us the same sample repeatedly on different days,

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then 95 per cent of the results that we would give

24

you back would be within plus or minus 2 standard

25



ANGUS, STONEHOUSE & CO. LTD.
TORONTO, ONTARIO

Ellis
cr.ex. (Symes)

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J14

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deviations. This is an expression of the variability
of the results that we would expect to give you
back.



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Q And you expect this in normal samples?

THE COMMISSIONER: Can this be translated - what would the result be? 95 per cent you say?

THE WITNESS: Okay. 95 per cent of the time the result would be expected to lie between 1.13 minus 0.28.

THE COMMISSIONER: 1.13?

THE WITNESS: Minus 0.28 and 1.13 plus 0.28.

THE COMMISSIONER: I don't understand the figure of 1.13, where does that come from?

THE WITNESS: This is an average value of the control material over the period of say 30 days, or 30 working days a month.

THE COMMISSIONER: Normally when you express that would you express it the way the Gallup poll does, the deviation you are going to have and 95 per cent is within 4 per cent or something of that nature, can you do that for us?

THE WITNESS: The range that that would give. Well, my arithmetic is not too good on the stand, but one in twenty times you would give us this sample you would be outside the range of two



K.2

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standard deviations. In other words, we would be outside the range of 0.8 is that to 1.4, one in twenty times.

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THE COMMISSIONER: You had better carry on, Ms. Symes, I am not doing you any good.

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MS. SYMES: Q. In both cases we are talking about normal curve be it a Gallup poll or repeated sampling in your quality control of dig levels, is that right?

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A. A gaussian distribution, yes.

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Q. So that is no matter whether you received a reading of 2.4, for example, which is within your therapeutic range, that still could be out up to .28 greater or .28 less, is that correct?

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A. When we start to get up to a high level, the formula for July 1980 was 0.21 for standard deviation.

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Q. 0.21?

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A. Yes. At a level of 2.24.

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Q. If the dig level is 2.24 --

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A. Right.

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Q. -- then the two standard deviations are 2.21?

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A. Yes. In other words we would expect to give you an answer somewhere between about 2.0 and 2.5, approximately.

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Q. So the very basic thing that we learn from this is that when you do sampling techniques, or you do repeated samples of dig levels in blood, you don't get the same answer time after time, you get it within a normal range, is that right?

A. You get it within a range, yes.

Q. And generally your experiences are that it is a normal range?

A. A normal range?

Q. Gaussian, you used.

A. Gaussian laboratory error is usually assumed to follow a gaussian distribution.

Q. And would you expect the same for Beckman kits?

A. Yes.

Q. There would be nothing unusual about Beckman, you would expect a gaussian distribution as well?

A. I would expect that, yes.

Q. Now, Exhibit 14, I believe I have the correct exhibit number on it, which was the "How To Do It", is that fair to say "How To Do It" from Antibodies Inc.?

A. Yes, a method from Antibodies Incorporated.



K.4

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MR. SCOTT: Have you got that, Doctor?

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THE WITNESS: Yes.

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MS. SYMES: Q. Now, this "How To Do It" is explained in words what Ms. Cronk wrote on the chart last Thursday, is that correct?

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A. Yes.

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Q. And I believe you told me at the break that the Beckman kit in fact does it slightly differently specifically from the charcoal part on?

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A. I believe that is the case, yes.

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Q. But the bottom line is both kits, the Hospital for Sick Children kit or the Beckman kit, measured the same thing, is that right?

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A. Both kits attempt to measure the same thing, yes.

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Q. And so whether or not Steps 5, 6 and 7 are different in the Beckman kit compared to the Hospital for Sick Children kit, you expect the same bottom line?

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A. Within a certain range.

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Q. Within a certain range?

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A. Yes.

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Q. Now as I read Exhibit No. 14, the "How To Do It" from Antibodies Incorporated, it talks about serum. It talks about where the unknown



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is serum, is that right?

A. Yes.

Q. Is it fair to say that this kit, or the antibodies from Antibodies Incorporated, were designed to test for therapeutic levels of digoxin in serum?

A. Basically they created an antibody in a rabbit to digoxin, whether you measure it in serum or whether you measure it in plasma.

Q. Particularly in Exhibit No. 14 they talk about using serum as the solution for the test.

A. Yes.

Q. And on page 3 for example, Item No. 5, see procedure No. 4, and on the fourth page calculations No. D, they talk about using serum.

A. Yes.

Q. Moving on in Exhibit No. 14, to the handwritten notes titled "1974", I presume then that the test from Antibodies Inc. also works on Plasma, is that right?

A. Yes.

Q. Now similarly the Beckman kit, and perhaps all other commercially available kits, they work on serum, is that right?



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A. Most kits designed for clinical purposes would be designed essentially for serum, or plasma.

Q. So they are designed to work on serum, is that correct?

A. Yes.

Q. And they are designed to work on plasma?

A. Yes, generally speaking.

Q. And how about whole blood?

A. Whole blood isn't usually the material used in most hospitals.

Q. Can I ask you the question: the kit, or the material from Antibodies Incorporated, was this "How To Do It" designed to be used on whole blood?

A. It wasn't essentially designed for that, no.

Q. It is not mentioned anywhere in it, and I am just asking you if there was a third set of material to say how to do it on whole blood?

A. These people are commercial people and they will direct their products to the appropriate market, and the appropriate market is usually serum or plasma.



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Q. All right.

A. It doesn't necessarily mean the thing won't work with any other solution.

Q. I am going to come to that. Can I add one more qualifier, was it for living patients?

A. Usually this is for therapeutic drug monitoring purposes.

Q. Yes.

A. So usually it is for living patients.

Q. So in other words the "How To Do It" in Exhibit 14, the company warrants then that the results that you get from using their kit are accurate within a normal range for serum?

A. Within a specified range.

Q. For plasma?

A. Yes.

Q. Provided they are from living patients?

A. Is that stated in the Beckman literature?

Q. No, no, I am asking you, is that when the company puts out this product do they warrant to people like the Hospital for Sick Children that the results that they get, using this technique, will be accurate provided they are used on serum, or



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plasma from living patients?

A. Yes, when the test is performed appropriately.

Q. Of course, according to the "How To Do It" in Exhibit 14.

A. According to an appropriate method, yes.

Q. Now, I presume that the same is from Beckman. Have you read the literature from the Beckman test?

A. No, I haven't.

Q. I want to ask you about all other kits then in general including Beckman in it. Do you know if any of the tests, the one you were using or any of the others were designed to measure digoxin in post mortem samples?

A. I know of no test that was specifically designed to do that.

Q. Do you know if any of these tests were designed to measure digoxin in tissues?

A. I know of no such test.

Q. Do you know if any of these kits were designed to measure digoxin in embalmed tissues?

A. No. There are several references



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to the tissues, the blood and the embalmed tissues where people have used kits. There are several references in the literature where kit methods have been used for those purposes.

Q. I am just going back to whether or not the manufacturer suggests, in any way, that their kit can be used reliably to measure digoxin levels in any of these?

A. Yes, I am not aware of any such kits.

Q. I am going to come to the literature. These were not for embalmed, but how about exhumed tissues?

A. I know of no instance where ---

Q. And is there anything, any of these kit manufacturers that suggest that these tests can be used for forensic purposes?

A. I am not aware of any. There are 20 or 30 kits and I haven't read each individual package insert.

MR. SCOTT: Just so we will be clear that the Doctor is being asked to comment on the description of the kits that he has read.

MS. SYMES: Exactly.

MR. SCOTT: Those descriptions will speak for themselves.



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MS. SYMES: Exactly.

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MR. SCOTT: And he is just being

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asked to summarize what he read.

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MS. SYMES: That is right.

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Q I am just asking you a short-

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hand rather than producing numbers of Exhibit 14,

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whether you can just tell us from your experience

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whether or not the manufacturers have said, use our

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A. It would not be good marketing

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policy for them to do that.

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Q Because people are not supposed

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to die?

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A. Well, because ---

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THE COMMISSIONER: They are not

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supposed to die of overdoses of digoxin.

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MS. SYMES: Q. Now, during the period

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July 1980 to March 1981, were you aware of any

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literature which measured the ratios of digoxin post

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mortem to digoxin ante mortem in blood, either serum,

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A. During the period?

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Q Yes.

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A. July 1980 to ---

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Q July 1980 to March 1981, were

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K.11

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you aware of any literature that had measured the
so-called multiplier effect?

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A. I was aware of I think two
papers at that time, one of which I cited in my
evidence at the Preliminary Inquiry. There have been
subsequent papers since. Oh, you are talking
specifically of post mortem as opposed to ---

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Q. Post mortem and ante mortem?

A. Ante mortem?

Q. Could you tell us at that time

what you believed to be the multiplier?

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A. At that particular time?

Q. Yes.

A. I would need to just look at

one or two pieces of information.

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MS. SYMES: Mr. Commissioner, I
obviously have, because of the normal -- I have to
revise it, I will be about another five minutes or so,
could I break now?

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THE COMMISSIONER: It is your "or so"
that worries me.

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MS. SYMES: I hope to be shorter than
that.

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THE COMMISSIONER: Well, if you can do
it in five minutes we will do it. Did you say you



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have an engagement elsewhere this afternoon, is that
for this afternoon?

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MS. SYMES: I have one at three, yes.

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THE COMMISSIONER: Certainly you
will get five minutes in between two-thirty and three.

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MS. SYMES: Okay.
THE COMMISSIONER: So why don't we
rise now. Could I see in my Chambers all of the
Counsel who have received a copy of the Atlanta Report,
could I see them right now, please.

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--- Luncheon adjournment at 12:45 p.m.



AA-1

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--- On Resuming.

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THE COMMISSIONER: Yes, Mr. Lamek.

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MR. LAMEK: Mr. Commissioner, perhaps

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I could interrupt the cross-examination of Dr.

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Ellis for a moment because, as you said this morning,

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there is something to be said about the Atlanta

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Report at this stage.

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Mr. Commissioner, on May 31st I

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gave certain reasons for not releasing the

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Atlanta Report until a later stage of these

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proceedings. Really those reasons amounted to two:

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there was a concern for those who might be

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adversely affected by the premature release of the

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Report before its authors were available for

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cross-examination and, second, there was a concern

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that other aspects of the Report should be read

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and understood against the background of prior

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evidence and not be put into a position of, perhaps,

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undue prominence.

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Mr. Commissioner, those concerns

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still exist and, in my submission, they are still

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valid, but to some extent events have overtaken us

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and the Centres for Disease Control which was the

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body which was retained to conduct the study which

led to the Atlanta Report featured in Time Magazine



AA-2

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2 in a very recent edition, as you well know, sir,
3 they are epidemiologists and the Report is an
4 epidemiological report. It contains interalia
5 medical assessments of the children who died and
6 whose deaths will here be reviewed, and it contains
7 considerations of a number of other epidemiological
8 factors, those in addition to certain matters which
9 were the cause of concern about unfairness and
adverse impact upon certain persons and organizations.

10 Now, sir, in the last few days
11 with
various counsel representing parties /standing before
12 this Commission have said that they believe that
13 they need to have access to the Atlanta Report in
14 order to be able intelligently to cross-examine
15 the medical experts who will begin to give evidence
16 within the next few days. In light of that, and
17 I'm certainly not prepared to say that they are
18 wrong in taking that position, but in light of that
19 it is proposed to do this, that is to say, to
20 distribute to all counsel an expurgated
21 copy of the Atlanta Report, expurgated to this
22 extent, there will be deleted from it only those
23 matters which might have an unfair, adverse effect
24 on certain persons if the Report were released in
25 total before its authors were here and available



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for cross-examination.

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There will be, in my judgment at least, and I have to ask counsel to accept my judgment for the moment on this, there will be nothing deleted which will in any way impair their ability to cross-examine the medical witnesses who will be called on a review of the deaths and that is the proposal, Mr. Commissioner, that I'm putting forward today. That does not mean that the authors of the Report will be here ten days from now. This is a release to counsel at an earlier stage than had originally been anticipated.

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I have to say that, as a matter of simple mechanics and physical capability, I cannot today distribute to all counsel the expurgated version of the Report. There is a simple, physical problem of preparing a sufficient number of copies of the Report in the form in which it is to be released, but I have every expectation that the version for release will be ready for distribution on Thursday of this week, sir.

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THE COMMISSIONER: Yes. Now, ladies and gentlemen, it is hard to tell whether an expurgated report is proper or not until you see the full document. You will see the full



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2 document in due course, not immediately, so I
3 cannot ask you to make any intelligent comment on
4 what Mr. Lamek has just said except to bear it in
5 mind for later complaint, and I have no doubt
6 there will be lots of it, but I cannot make any
7 other recommendation to you.

8 Yes?

9 MR. STRATHY: A point of
10 clarification, Mr. Commissioner. Do I take it
11 from what Mr. Lamek has said that it is being
12 released to counsel on the basis that it is being
13 released to counsel, and it is not being released
14 to the public generally, It was indicated in Mr.
15 Lamek's opening that at some future date when the
16 authors were called it could be released?

17 MR. LAMEK: Mr. Strathey's question
18 is an entirely proper one of course and I should
19 have made that clear. Yes, that is the decision
20 that has been reached at this time, that the
21 Report will be released to counsel but not yet
22 marked as an exhibit. It is the present
23 expectation that when the Report's authors are
24 present and have given evidence then the Report
25 in its complete and unexpurgated form will be marked
as an exhibit and will be generally available.



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It may be that events may occur before that time to make it appropriate to mark the expurgated version as an exhibit. I'm not about to prejudge or anticipate the likelihood of those events occurring, Mr. Commissioner.

I should also say that the Report in the form in which it will be distributed having been given to counsel, then of course it is understood that they are free to discuss the Report with their clients, with such advisers as they think appropriate and necessary, and to make the kind of use of it for which it is being distributed, to enable them to prepare for cross-examination on all the evidence that is to come.

THE COMMISSIONER: Any problems?
All right. Ms. Symes.

MS. SYMES: Q. Before we broke for lunch, I had asked you the question, if you were aware in the period, first of all, from July 1980 to March of 1981 of any literature concerning the measurement of the ratio of digoxin, post mortem and there were two, digoxin ante mortem, in serum or plasma, what I call the so-called multiplier effect?

A. I was aware then and I am aware now of an article in the Journal of Forensic Science, 1978, Volume 23, pages 329 to 334.



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2 This relates to the question you have raised.
3 Blood was taken pre-mortem and also post mortem and
4 I have not had an opportunity to go through this
5 in great detail but in the result section on page
6 330, the mean post mortem to ante mortem ratios were,
7 1.96 for heart; 1.63 for subclavian; 1.42 for
8 femoral samples of blood.

9 So if you say that heart blood is
10 approximately twofold the value, and again I think
11 this depends very much on the method of collection,
12 and I think that it would be better to have a word
13 with Dr. Phillips or Dr. Soldin, perhaps.

14 Q. Perhaps you might tell me,
15 does this article differentiate in the size of the
16 multiplier, depending on when the post mortem sample
17 was taken?

18 A. Offhand, I don't know. I
19 cannot say that. I could present this article to
20 you if you so wish.

21 Q. As a matter of fact I was
22 wondering if perhaps we could mark it as an
23 exhibit, if it is useful. It is the only firm thing
24 we have on the so-called multiplier effect, and
25 perhaps copies could be made. Would that be
agreeable?



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THE COMMISSIONER: It can always be done. Usually if you want it, sight unseen, as an exhibit, that is not usual. Would you like to read it?

MS. SYMES: I certainly would.

THE COMMISSIONER: Why don't you take it and read it and then if you find that it is of assistance --

MS. SYMES: Q. I have asked you about the period from July 1980 to March of 1981. After that, March of 1981, do you have any further information other than the article that you have just cited?

A. I have not really made a study of this. There may well be literature out there but I'm not aware of anything that directly relates to that that I could give you at this time.

Q. Has the Hospital for Sick Children, for example, done its own study?

A. I think its own study has been done, yes, whether it relates specifically to that issue I am not sure.

Q. Who is the person to ask those questions of?

A. Dr. Phillips of Pathology and



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Dr. Soldin of Biochemistry.

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Q. The second question, in the same period, from July of 1980 to March of 1981, were you aware of any literature with respect to the ratios of digoxin in tissue to digoxin in blood, first on post mortem, both being post mortem?

A. There are a number of articles that relate to this. Exactly when I became aware of these is rather difficult to define.

Q. The second question is only whether or not there has been any breakthrough in the information, but why don't you tell us then what the literature says about these so-called ratios?

A. Certainly the tissue levels are very much higher than blood levels - plasma levels, but it is variable, depending on whether you are dealing with a child or an adult; and perhaps we could get to your third question and then I will present the real information I think you probably want.

Q. It helps when you can ask the questions first.

A. Okay.

Q. Dr. Ellis, the third question of course that I want to ask you, is the ratio of



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digoxin in tissues to digoxin in the blood, both
ante mortem?

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THE COMMISSIONER: Are we hearing
the first night of a play after a long rehearsal?

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MS. SYMES: We're trying to
co-operate to cut down on the length of the cross-
examination.

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THE WITNESS: I think there was a
very significant paper in May of 1982 that you may
have been aware of already.

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MS. SYMES: Q. Since it is not part
of the public record, why don't you tell us about
that?

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A. This is the American Journal
of Diseases of Children and it is Volume 136, in
May 1982, page 418. It relates to myocardial
versus serum digoxin concentration in infants and in
adults.

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Q. Just so I can understand what
the numerator is, is that tissue from the heart?

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A. This is tissue from the heart
taken at operation.

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Q. So, this is of a living patient?

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A. Yes.

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Q. And this, then, is serum or



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plasma?

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A. The serum or plasma level at the time, yes, or shortly before the operation.

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THE COMMISSIONER: Can you take tissue from the heart of a living patient?

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THE WITNESS: There was an operation on the heart of these patients and, in the course of that operation, a small amount of tissue was taken.

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Basically, perhaps if I could summarize these, the authors reported that there was no difference in the serum digoxin levels for the two groups; in other words, the infants and the adults, but they did find, however, that there was considerable difference in the myocardial digoxin levels.

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THE RAA, in other words, the right atrial appendage which was the area of the heart that was removed, digoxin levels were 211 nanograms per gram of wet weight in the infants but only 35.1 nanograms per gram of wet weight in the adults. There is a range, obviously, for this.

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MS. SYMES: Q. I'm sorry, are you giving me again ratios?

A. Yes.



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Q. Just so I can understand, in a child, then, the ratio of digoxin in the heart tissue, the right part of the heart --

A. Sorry, thank you. I stand corrected on that.

That particular number that I gave you was nanograms per gram of wet weight.

Q. Yes.

A. So, actual ratio would need to be divided by the mean digoxin concentration.

Q. Do you know what the digoxin concentration in the blood was, so that we can work out the ratio?

A. Perhaps if I could refer to Table 1 where this actual RAA serum ratio is given.

Table 1 relates to infants and this ratio is stated at the bottom of that table to be 149 plus or minus 31, with the 31 being the standard error for the mean.

Q. The ratio is 149 to 1?

A. Yes.

Q. So that is the ratio of digoxin in tissue to digoxin in plasma?

A. In the serum of these infants that they measured, yes.



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Q. And the standard deviation
there is -- is it 31?

A. The standard error of the
mean is 31.

Q. That is a rather large
standard error, is it not?

A. Not really. There is
variability, obviously; biological variability.



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Q. Now, what is the ratio for adults?

A. In Table 2 of that same paper the mean value is given as 28, plus or minus 5. For the concentrations of digoxin in the right atrial appendage in the serum in adults.

Q. So, in other words, the ratio for children is at least five times the ratio for adults?

A. On average, yes.

Q. On average.

A. Yes.

Q. Now, let me just start then with an example then when you might have post mortem. Was there anything in that study with respect to the ratios of post mortem tissue to post mortem blood, or is it serum?

A. I don't know whether it was covered in the study.

Q. Do you know of any other?

A. In the references given in that particular paper there may well be references to autopsy samples.

Q. But other than that particular paper, are you aware of anything else in the literature?



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A. There are one or two studies which I think many are related to in the references to this particular paper.

Q. So then if we read that paper, that would give us the latest knowledge in this area.

A. I think that this will be an important paper to consider.

Q. Now, Dr. Ellis, just so I understand, have I got it correct that there are two factors then that work when we look at results on tissue or blood or plasma post mortem; one factor is that it is no longer living, that is, there is a multiplier of fact which is about 2 between pre-mortem and post mortem on blood?

A. That's the approximate figure used in the paper that I cited, yes.

Q. And then there is a second factor then and that is the difference or the ratio of digoxin in the tissue to digoxin in the blood and that can be as much as 149 to 1 in infants.

A. The average ratio was 149 to 1. There is Case 4, which I think is the highest where it is 363.

Q. 363?



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A. Yes, if I'm reading this table correctly.

Q. So that when we look at any specific results of post mortem levels of digoxin in tissue, we should certainly have these ratios in mind?

A. Well, these are taken for living tissue and obviously they would have to be seen in context.

Q. Now, do you know if there's been any studies done on the effects of embalming on digoxin in blood and tissue?

A. I've only come across one paper where an embalmed tissue was studied or a patient had been embalmed. What was your question?

Q. Can you tell us about it and what the study found happened to digoxin in embalmed either fluid or tissue?

A. Well, it wasn't really a very detailed study. I'm sorry, I did have that paper a little while ago. Could you please ask me another one?

Q. Yes, I was going to ask you whether or not any studies have been done on the effects over time of digoxin in blood and tissues of



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exhumed?

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A. I don't know of any.

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Q. You don't know of anything?

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A. I don't know of any, no.

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Q. And since ---

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A. Oh!

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Q. Have you found it?

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A. I have found a reference to it
but not quite the exact article.

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Q. Could you give us the reference

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then for the record?

12

THE COMMISSIONER: If he's going

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to give us the reference for the record, he should

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give us the document itself.

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MS. SYMES: I'm going to ask him

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to do that as well.

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THE COMMISSIONER: Well, we have

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passed by all kinds of documents without making

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them exhibits. However, you see, this isn't like a

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trial. You can produce the document at any time you

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like. You can put it to a witness and do whatever

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you want but if you've got something you want to

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prove by it, it is perhaps best to give it to us at

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the time.

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MS. SYMES: I think it is perhaps,



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2 because these ratios are so significant in the next
3 stage that it would be helpful if we could mark as
4 exhibits the particular scientific papers that he's
5 relying on.

6 THE COMMISSIONER: All right.

7 MR. LAMEK: Referring to I think is
8 the word.

9 THE COMMISSIONER: Referring to.

10 THE WITNESS: Well, do you wish to
11 mark one of these as an exhibit?

12 MS. SYMES: Could we mark then the
13 first one?

14 THE WITNESS: Do you wish to read
15 it?

16 MS. SYMES: The measuring of
17 ratios of digoxin post mortem to digoxin ante mortem
18 in blood. Could that be the next exhibit?

19 THE COMMISSIONER: Yes, but what is
20 it from?

21 MR. SCOTT: Well, we don't have a
22 clean copy, but we can get you one.

23 MS. SYMES: Sure. Could we reserve
24 then a number for that?

25 THE COMMISSIONER: Yes, all right.
Well, we don't need to reserve a number for it



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because we can put in any number as we come along.
That was Miss Cronk's idea that we had to reserve
things, I don't think it's essential.

MS. CRONK: Another bad one
apparently, Mr. Commissioner.

MS. SYMES: Q. Dr. Ellis, could
I simply ask then if you would get clean copies of
the three studies that you referred to and give them
to Mr. Scott who could then supply them to counsel?

A. What do you mean by a clean
copy?

Q. Well, he says they're marked.

A. They are marked actually, yes.

Q. I don't mind if they're marked,
but if he does.

MR. SCOTT: Well, I will see that
Miss Symes gets copies. I hope that this literature
search is not going to go on forever.

THE COMMISSIONER: Well, I hope it
isn't too.

MR. SCOTT: Because I feel an
obligation to my clients to assure that this
professional and the others who will be called to
the witness box goes back at some point to perform
his duties in running a hospital.



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BB7 THE COMMISSIONER: Yes. I think, I hope that it won't be just your clients that will go back to perform their duties, whatever they may happen to be. I think all of us may have an interest in that.

The only problem, and I'm not saying you're cluttering up the record, but I will not promise that I will read these documents from beginning to end. You have to point out to me what it is that we want and what it is that you're relying on, if you are relying on it, and then it becomes a great deal more help.

However, I think we have extracted from Mr.Scott the promise to do something about clean copies, if he can find one.

MS. SYMES: Dr. Ellis had said over the lunch hour that he had this information, that he would provide it to us.

THE COMMISSIONER: Yes,all right.

MS. SYMES: So, I didn't want to seem to be in the position of asking him to go out and search the literature, he said he already had it.

THE COMMISSIONER: Yes, all right.

THE WITNESS: The paper in relation to the embalmed subject is in the Forensic



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Science, Volume 9, 1977, page 145 to 150, post mortem digoxin levels, two unusual case reports. I know of no other case. It was Case 2 in that particular article.

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MS. SYMES: Q. Dr. Ellis, I had asked you before whether or not the kits from the manufacturers were, according to the manufacturer, designed to measure digoxin in post mortem blood, tissues, embalmed tissues and exhumed tissue and your answer to that was, not to your knowledge.

A. That's correct.

Q. Would you agree with me that the current state of knowledge with respect to the measurement of digoxin in these items, that is, post mortem blood or plasma or serum, tissues, embalmed tissues or exhumed tissues is still uncertain?

A. It would require a certain amount, several months work in order to adapt a method for use with those tissues and substances, in my view.

MS. SYMES: Those are my questions.

THE COMMISSIONER: Yes, all right, thank you. Mr. Strathy, are you next?

MR. STRATHY: Yes, Mr. Commissioner.



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CROSS-EXAMINATION BY MR. STRATHY:

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Q. Dr. Ellis, the article you just mentioned from Forensic Science, I wonder if I might see that?

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A. Was that relating to embalmed?

7

Q. Yes.

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A. Yes.

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Q. I will give it back to you before the end of the day.

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Doctor, I don't have your curriculum vitae in front of me, but I think I'm correct in recalling that you are a PhD doctor and not an MD doctor, is that right?

14

A. That's correct, yes.

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Q. And you quite properly pointed out in your evidence the distinction between what you conceived your responsibilities to be in the hospital and those of the MD doctors and I think you pointed out that as far as you saw it, your responsibility was in the analysis of the digoxin levels in the samples submitted to you. Do I have it right as far as your responsibilities are concerned?

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A. Yes, I think that was my major responsibility, yes.

24

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Q. And you pointed out that the



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2 responsibility of the MD doctors was in effect the
3 interpretation of those findings or analytical
4 results.

5 A. Well, it was their responsibility
6 with the patient in front of them, the clinical
7 condition of the patient and the result in hand,
8 knowing what the previous therapy was, to take the
9 appropriate action, yes.

10 Q. And in fact, not only to take
11 the appropriate action but firstly before doing that,
12 to interpret the results in light of the observations
13 they made.

14 A. Yes, in the individual case.

15 Q. And do I gather from what you
16 have said that the interpretation of those results
17 may involve not simply looking at the results but
18 also looking at the patient, looking at the symptoms
19 being manifested, looking at the past history and
20 so forth?

21 A. Yes.

22 Q. Am I correct in understanding
23 that in the time period with which we are concerned,
24 namely, July, 1980 to March of 1981, digoxin testing
25 was only done firstly on those patients who had
been prescribed digoxin, but secondly, only on the



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request of the treating physician, is that right?

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A. Yes, that's correct.

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Q. So, your laboratory really

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had nothing to do with whether or not a request

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was submitted for analysis, you just did what the

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doctor told you to do?

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A. Generally speaking. As I

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indicated, there were one or two occasions when we

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would contact the floors and say this is a high

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result and perhaps suggest that a further sample

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may be taken. But this was not on very, very many
occasions.

13

Q. But that was generally after

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the fact, after the sample had been submitted to you?

15

A. Oh, yes.

16

Q. Do I understand in fact that

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at the present time that is still the procedure, that

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doctors order their tests to be made and you do it
on the doctors' orders?

19

A. This is the case, yes. But

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there is a mechanism in place whereby the clinical

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pharmacology group examine the results as they are

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produced, the abnormal results, and they may intervene

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at some stage and actively discuss with the floor

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staff the condition of the patient and the

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appropriateness of the level that has been obtained.

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Q. That is a new procedure, is it.

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A. This is a new procedure, yes.

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Q. Is it as a result of this
therapeutic drug monitoring program that we've
heard about?

7

A. Yes, yes it is.

8

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Q. So that there are occasions
when the clinical people, or your staff take the
initiative, and having seen an unusual result they
actively go out and request more sampling, do they?

11

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A. The clinical pharmacology group,
yes.

13

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Q. Is that something other than
your people?

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A. Yes.

17

Q. Who are the clinical pharma-
cology group under?

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A. They are members of the
Division of Clinical Pharmacology, which I think is
part of the Department of Pediatrics, or it may be
part of the Research Institute, I'm not sure on that
point.

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Q. Can you assist me, Doctor, as
to when it was that you first became aware that there



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2 might be problems at the Hospital for Sick Children
3 with respect to elevated digoxin levels in certain
4 children?

5 A. I believe that it was ---

6 MR. SCOTT: Just before the
7 witness answers. I just again want to record, and
8 it will be for the last time because I will leave it
9 to Commission Counsel, that it wasn't my understanding
10 that this kind of question was going to be dealt
11 with here today, we were going to deal with the
12 testing mechanism in place and its operation and
13 so on. If that rule has been changed, we had better
14 know because it will affect everybody's cross-
examination.

15 THE COMMISSIONER: No. Well, it
16 hasn't been changed, Mr. Scott, but I don't imagine
17 you are going to go deeply into the specifics, it is
18 the general question and then perhaps whatever took
place after the general question.

19 MR. STRATHY: That's exactly so,
20 sir.

21 THE COMMISSIONER: Yes, all right.

22 THE WITNESS: In relation to the
23 general question, I think I have answered this
24 question at the Preliminary Hearing before. I think
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the first occasion when I realized when somebody
indicated to me that something may be wrong was
when Dr. Costigan was pursuing the Kevin Pacsai
case in about, would it be February or March of 1981,
March, I think.



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Q. I don't have the date of
the death of Pacsai - I believe it was sometime
in mid-to-late March sometime.

A. I think it was early March.

Q. So, was it sometime after the
death of Kevin Pacsai?

A. Yes.

Q. Prior to that --

THE COMMISSIONER: In the Statement
of Facts, I think, is there not a date, if that
matters at all, but I think it is right there, is
it not?

MR. STRATHY: I don't have the
Statement of Facts with me.

MS. CRONK: Mr. Commissioner, to
assist my friend, the date of death is shown as
the 12th of March 1981, Kevin Pacsai.

THE COMMISSIONER: I thought there
was something in the Statement of Facts about that
particular --

MS. CRONK: In addition to the date
of death, sir?

THE COMMISSIONER: The events of
March 21st, et cetera.

MS. CRONK: Yes, there is, sir.



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THE COMMISSIONER: What page is that on?

MR. LAMEK: Page 46, Mr. Commissioner.

MS. CRONK: I think you are also referring, Mr. Commissioner, to paragraph 100 on page 88 of the Statement of Facts, which speaks about Kevin Pacsai's death.

THE COMMISSIONER: Yes, March 12, 1981, the Coroner was consulted upon his death.

From whom did you hear this?

THE WITNESS: If my recollection is correct, Dr. Costigan, who was a Cardiology Fellow or Resident on the ward at that particular time.

THE COMMISSIONER: Yes. All right.

A.: The question was, when did he die?

MR. STRATHY: Q. Yes.

I take it from what you said, then, it was sometime within a short time after the death of Kevin Pacsai on March 12, 1981?

A. Yes.

Q. Do I understand then that prior to that time, you had no inclination or suspicion or concern that there was any problem with respect to digoxin in the treatment of children at the



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Hospital For Sick Children?

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A. Yes.

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THE COMMISSIONER: Yes, you had not?

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THE WITNESS: I had no fear or
inclination that there might be any problem.

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MR. STRSTHY: Q. Based on the
analysis which you had been conducting or based on
any other information that came to your attention?

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A. Yes.

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Q. Now, you mentioned in the course
of your evidence both last day and this morning
your brief incursion into the area of analysis of
tissue levels of digoxin.

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A. Yes.

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Q. Can you indicate when it was
that you made that investigation?

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A. I think it was fairly shortly
after that time.

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Q. Sometime shortly after March
12th?

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A. Yes.

Q. And was that on the request of
the Metropolitan Toronto Police?

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A. No. I have a feeling that was
initially at the request of the cardiologist - I think



CC4

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2 it was Dr. Freedom. He was concerned about these
3 matters.
- 4 Q. Dr. Freedom asked you to test
5 tissue samples, did he?
- 6 A. I think that was the case, yes.
7 I indicated we had no experience of that, and he
8 said, well --
- 9 Q. I'm sorry, you indicated to
10 Dr. Freedom --
- 11 A. Yes.
- 12 Q. -- that you had no experience
13 of that?
- 14 A. Right.
- 15 Q. And what was his response?
- 16 A. Well, very often, we are asked
17 to do these kinds of things. The question is to
18 try it and see what happens. If we are successful,
19 we believe we have an answer that we are happy with,
20 then we communicate this information to people
21 and, if we don't, then--well, circumstances overcame
22 it.
- 23 Q. What was your response to
24 Dr. Freedom?
- 25 A. He indicated, I believe, at
that time that some samples had been taken at



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autopsy from some children. These were in some material, some medium in the Biology Department at the Hospital and, so, these were samples that had not been subjected to formalin, I think, and the various preservatives.

Q. Yes.

A. And could we take a look at those on a preliminary basis.

Q. And did you do that?

A. We attempted to do that, yes.

Q. And this is when you came up with the equivocal result you have told us about?

A. Yes.

Q. What then did you do? What did you tell Dr. Freedom?

A. I don't think Dr. Freedom got back to me because I think circumstances overtook us.

Q. What do you mean by that?

THE COMMISSIONER: I don't see Mr. Scott standing.

MS. CRONK: I'm afraid Miss Cronk is, Mr. Commissioner.

I do have -- I hesitate to interrupt my friend in the middle of his cross-examination. It is the expressed intention to ask Dr. Ellis to



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return to testify in as much detail as required about specific testing results that were obtained in respect of the particular deaths that we are concerned with.

Now, if I am wrong in my apprehension of his evidence, these tissue tests were taken not in respect to these children and at a time after March 1981, then I withdraw any comment.

As I have understood Dr. Ellis' testimony in the last five minutes, he is talking specifically about tissue tests done in respect of these very children in March of 1981, and I would suggest that this line of enquiry would be more appropriately pursued when he comes back to talk about, generally, the testing that was or was not done.

THE COMMISSIONER: Well, Mr. Strathy, if you need any more than the fact that the first time was in March after the Pacsai death and that he did examine some tissue post mortem.

MR. STRATHY: The only other question, a few other questions I want to ask of him - and I don't want to get into specific tests --

THE COMMISSIONER: No.

MR. STRATHY: -- but I want to ask



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him the same question I did ask him; what was his response to Dr. Freedom, or what was it that intervened, I think was my question; what event overtook him.

MR. SCOTT: I didn't get up because I was told this wasn't going to happen. It seems to me, as a matter of principle, the line has to be drawn in fairness, not only to the witness and to the orderly conduct of the Commission's business, but in fairness to other counsel.

THE COMMISSIONER: Yes, I agree.

MR. SCOTT: Because, if this is allowed for one counsel, the dike has been breached and we are here for days.

MR. STRATHY: I will simplify it, sir. I will simply make a note to ask the question when the witness returns and we will leave it at that for now.

THE COMMISSIONER: Thank you.

MR. STRATHY: But I do have one last question in this vein.

Q. You did tell us, Dr. Ellis, that you concluded that a great deal more work would have to be done before a system could be devised to test for digoxin tissue, and I think you told my



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- 2 friend, Miss Symes, that you concluded that it might
- 3 take a couple of months to do that sort of thing.
- 4 A. I think it may well have done,
- 5 yes.
- 6 Q. What was it, in your view,
- 7 that would have had to be done to devise a test for
- 8 the measurement of digoxin in tissue? Can you tell
- 9 us what you foresaw would have to be done?
- 10 A. Is this an appropriate question
- 11 to answer?
- 12 Q. Nobody is objecting.
- 13 THE COMMISSIONER: Usually, we have
- 14 five or six people objecting to the question, and we
- 15 haven't anybody at the moment except you.
- 16 A. I guess I would have had
- 17 to consult the available literature extensively
- 18 and see how various people have approached this
- 19 problem in the past and, then, depending on the
- 20 various approaches, I would have had to test one or
- 21 two things that looked likely and see where we went
- 22 from there. Basically, that is a lot of time
- 23 spent, or it would have been a lot of time spent,
- 24 in my view.
- 25 MR. STRATHY: Q. What do you mean
- by "test one or two things that looked likely"? Do



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you mean test one or two methods?

A. One or two methods, one or two extraction procedures; different approaches to obtaining a pure sample.

Q. Is there anything else that you saw as being necessary before you would be able to develop a methodology?

A. Well, a very extensive literature search, as I say, of the resources and available time and some inclination to do it and some indication to do it.

Q. Were you approached by the Metropolitan Toronto Police to do that sort of thing?

MR. SCOTT: Now, surely, Mr. Commissioner, this has --

THE COMMISSIONER: It is getting very close.

MR. SCOTT: This is coming very close to where my friend has to follow the rules laid down by the Commission or ask you, Mr. Commissioner, to change them. Until they are changed, I think they should be followed.

THE COMMISSIONER: You have been promised, Mr. Strathy, that Dr. Ellis will be back and we will be dealing with the individuals.



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Unfortunately, every time you ask one of those questions, it is possible to interpret it that you are trying to get information on the particular --

MR. STRATHY: I am really -- With all respect, Mr. Commissioner, I am not asking--I haven't named a child with only one exception. I haven't asked for specific results and I hope I have been dealing with what one would consider background. It is kind of hard to draw the line between the background and the foreground.

MR. SCOTT: I'm sorry. I have been doing my best to keep as quiet as possible and, this afternoon, I have ruined my record!

If I understood the rule proposed, it was that we would deal in a general way with testing methods known at the time and, then, later in the inquiry, we would deal with the events that give rise to these tragic circumstances.

Now, this question bears clearly on the events.

THE COMMISSIONER: Yes. But it may also bear equivocally upon the method of determining results. That is the way he is getting his foot in the door, this way.

MR. STRATHY: I asked the same



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question precisely of Mr. Cimbura, and I don't think anybody raised an objection.

THE COMMISSIONER: Perhaps Mr. Scott was not here at the time.

MR. SCOTT: I didn't act for Mr. Cimbura.

THE COMMISSIONER: I'm going to allow this question and then we will see what happens after that.

You can go so far, but there comes a time when I have to stop you.

MR. STRATHY: I think I can rephrase my question or put it to you again, Dr. Ellis.

Q. Were you approached by the Metropolitan Toronto Police and asked to analyze any tissue samples?

A. Any tissue samples specifically?

Q. Yes.

A. I don't think I personally was approached by the Metro Toronto Police. I believe there were discussions in the Hospital at around this time which the Metro Toronto Police did request that various measurements of digoxin be made. I think perhaps tissues did come up at this stage.



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I believe, that, following some preliminary fluid analyses, my head of department felt it was inappropriate for me to continue with that work, largely because he realized how much time it would take, I think, and largely because he also appreciated that we had no experience of this and also because it was felt that, really, this should be done by an impartial body outside the Hospital For Sick Children. I understand that one hospital - perhaps Toronto General - was asked if it could measure some samples of digoxin, but I don't know quite what came of that.

Q. Just to refresh my memory, your head of department at the time was?

A. Dr. Goldberg.

Q. And it is your understanding, although you are not privy to the discussions, that, indeed, a request was made by the Metropolitan Toronto Police?

A. I think they may not have realized how big a task they were asking for.

Q. Be that as it may, the request was made?

A. Perhaps you could ask the Metro Toronto Police exactly what they asked.



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Q. I guess you are the only one
we have.

A. Well, I'm giving hearsay
evidence.

THE COMMISSIONER: The only one we
have in the box at the moment. We certainly will
have the Metropolitan Toronto Police in eventually.

MR. STRATHY: Q. To put it fairly,
doctor, it is your understanding at least the request
was made?

MR. SCOTT: He said, not to him.

THE COMMISSIONER: It is hearsay on
top of everything else. While we allow hearsay
at enquiries, there is nothing in the Act that says
the Commissioner has to pay any attention to it.

MR. STRATHY: For whatever weight
it is worth.

A. I'm sorry, what was the
question again?

Q. I said, is it your under-
standing -- I mean, do I have your understanding
correct that, at the time, a request was made by
the Metropolitan Toronto Police?

MR. SCOTT: I think that is an un-
fair question. The people, if the request was made,



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the people who know about it are going to be
available and they will be asked, but to ask someone --
Mr. Strathy, you might as well ask me what my
understanding was.

MR. STRATHY: Yes.

MR. SCOTT: We should ask this
witness things about which he has personal knowledge.
That is why he is here.



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THE COMMISSIONER: All right. Did you appreciate that advice or not?

MR. STRATHY: I appreciate the advice, but I guess Mr. Scott cannot give an undertaking on behalf of the Metropolitan Toronto Police.

MR. SCOTT: The Hospital will make available any witness, I am certain, that Mr. Strathy wants to examine.

MR. STRATHY: If Mr. Scott then can say that Dr. Goldberg will be available, then I will hear from Dr. Goldberg. That is fine. I will accept that.

THE WITNESS: The request made --

MR. SCOTT: I will show you how to draw a subpoena.

THE COMMISSIONER: That won't do. It has to come through me, these subpoenas.

MR. STRATHY: That is fair. I have Mr. Scott's offer and I will respectfully take him up on it. Thank you.

THE WITNESS: I indicated Goldberg's decision. I did not indicate, I do not think, that Dr. Goldberg was the person specifically asked to undertake this task and in fact I believe that this question was really asked of Dr. Hill and the Hospital Administration.



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THE COMMISSIONER: In any event, I think we have pursued it far enough.

MR. STRATHY: Q. Moving on to another area, Doctor, and dealing with the subject of interpretation of digoxin levels, I gather that the treating physician wants to know the digoxin level for two reasons: one to make sure that the patient is not toxic or at a toxic level and, secondly, to make sure that in fact the patient has enough digoxin in his system. Is that right?

A. Yes.

Q. I am instructed that, because perhaps of its potency, digoxin toxicity can be a problem in hospitals. Is that something with which you are familiar?

A. Yes, this is why many hospitals measure digoxin.

Q. You say many hospitals measure digoxin?

A. Many hospitals would measure patients plasma for digoxin because there is a problem, as indicated.

Q. A problem with toxicity?

A. Yes, with potential toxicity.

Q. I have seen figures, at least in



DD.3

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the literature, that suggests that with respect to

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adult patients in hospitals you can have as many

4

as 10 per cent or even 30 per cent of the patients

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on digoxin therapy at toxic levels. Are you familiar

6

with that literature?

7

A. Not that specific figure, but --

8

Q. Would it be fair to say, in any

9

event, that you are familiar with the fact that you

10

may have a high proportion of patients at toxic levels,

11

based on the literature?

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A. I think it is really quite

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variable from hospital to hospital and patient to

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patient.

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Q. Let us deal with your hospital

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then, let us be specific. Are you able to assist us

17

as to the levels of toxicity at the Hospital for

18

Sick Children, with respect to patients receiving

19

digoxin therapy?

20

A. Am I able to assist you with

21

the levels of toxicity?

22

Q. Yes. What proportion of the

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patients receiving digoxin therapy would be at or

24

above toxic levels?

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A. At any given time?

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Q. At any given time, based on your

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experience?

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A. I do not think I can give an answer to that question. There may be perhaps one or two in about ten or twenty.

Q. Are you able to give us a range in terms of percentages?

A. No, not really.

Q. I suppose that in your record books and I do understand that your samples that are tested on a regular basis, the results are recorded in record books kept in your Lab?

A. Yes.

Q. And I believe in fact --

A. Or in Dr. Soldin's lab or somewhere between the two.

Q. A laboratory, in any event, and I gather that those record books were filed as an exhibit at the preliminary inquiry?

A. In relation to the period under discussion, yes.

Q. So by looking at those exhibit books we will have a reasonably good idea as to what the number of patients at or above toxic levels were during that time?

A. Yes, and also if you look at the preliminary inquiry evidence, I was asked to



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report - there were about five. Now, admittedly it does not report on whether it was between 2.5 and 5 or 2.0 and 5 but it may give you some indication over that period of time, or subsequently.

Q. In the course of that inquiry you gave evidence on that very point, then?

A. Yes.

Q. The number over that level.

A. About 5 nanograms per ml.

Q. But you cannot tell us today as to the number or the range of patients that fell in that category?

A. No.

Q. I was not sure from your evidence, particularly as it came out this morning in cross-examination by Mr. Bogart, as to exactly the procedure that was followed when you did your analysis, and I would assume, firstly, that when you do a run of samples, tests, you are really trying to find out, among other things, whether the child is at a toxic level, so your primary concern would be, is this child toxic. Is that fair?

A. Does this child have a level that could be out of the therapeutic range.

Q. Out of the therapeutic range,



DD.6

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and that is the reason why you would call the floor
and tell them that, if you found that as a fact?

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A. I think I indicated last

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Thursday that at the particular period of time that
we are discussing all reports were telephoned as soon
as they were available.

6

7

Q. On every child?

8

A. Yes.

9

Q. Your primary concern however is

10

whether the particular child is toxic?

11

A. My particular concern?

12

Q. The reason you were doing the

tests is to find out whether the child is toxic?

13

A. Yes, or sub-therapeutic.

14

Q. My question is whether or not

15

as a regular matter you did a further dilution, that

16

is, suppose your first test shows you that the child

17

is about 4.7 or 5. As a matter of routine, would you

18

invariably do a further dilution, or would you simply

19

say, well, the child is toxic, we know that, we don't

20

need to do a further dilution?

21

A. I think that at some stage we

22

elected not to report - we elected not to go any

23

further than the initial sample. Then we got further

24

and further into this problem and we started to dilute

25

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DD.7

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one in two and one in five and so on.

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Q. Do I understand then that at some point in your regular routine therapeutic monitoring you satisfied yourselves basically with the one testing?

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A. Perhaps, you know, back in 1977 or 1978. I am not quite sure. It would also depend on sample availability, of course.

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Q. What I need to know, please, if you can help us at this point is, let us take the period July 1980 to March 1981. During that period, as a matter of routine, did you simply take the one test on each sample or did you do dilutions as a matter of routine?

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THE COMMISSIONER: Where necessary.

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MR. STRATHY: Q. Where necessary?

A. I think it was a matter of routine to do the dilutions. If you brought me instances where we had reported greater than five and had not pursued the matter further, then I would not say that that had not happened. I do not remember every single result that goes out of my Lab or every single procedure that was in place two years ago.

Q. That is absolutely fair, but I take it that today at least your recollection is that



DD.8

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as a matter of routine you did do a further dilution?

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A. Yes, in many of the instances,

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as we will come to later, we were doing further
dilutions.

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6

Q. And I take it we will see

those further dilutions in your record books?

7

A. Oh, yes.

8

9

Q. I take it the ability to further

dilute is subject to that one qualification that you
have mentioned already, namely that there be enough
specimen or sample available to do it?

10

11

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A. Yes, I think so. The other

qualifier might be that if we were to determine that
a sample had been taken at an inappropriate time
there might not have been any further indication to
further dilute that individual sample.

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Q. I would like to ask you about

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that because you mentioned in your evidence last day

18

that on occasions where you had found abnormally high

19

digoxin levels as part of your routine monitoring, you

20

yourself would contact the ward, and I think you

21

mentioned that in some cases those were explained by

22

recent administration of digoxin?

23

A. Yes.

24

Q. Thereby inflating the digoxin

level?

25

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DD.9

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A. Yes.

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Q. I take it from what you have

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just said that when you found that out, that there had

5

been recent digoxin administration, you might not

6

bother performing a further dilution?

7

A. That is correct, yes.

8

Q. But do I also understand that

9

there were some cases where you yourself inquired of

10

the ward about high levels and did not discover there
was recent administration?

11

A. There may be indications like

12

perhaps the child went into renal failure - kidney

13

failure - at the time the blood was taken or shortly

14

before, and so digoxin had been given, which was quite
appropriate, but the child's condition changed.

15

Q. So that would be something,

16

renal failure, for example, that to you on inquiry

17

would explain high levels?

18

A. Yes.

19

Q. Was there anything else that

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you discovered during that period in the course of

21

these inquiries which you made which accounted for
high levels?

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A. Nothing that immediately comes

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to mind.

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Q. Do you recall any occasions where you saw high levels, sufficiently high levels to peak your curiosity or give you concern, that were not explained in some way by the ward staff or the treatment that you observed?

A. I can't think of any offhand. We are not talking autopsy samples here, are we?

Q. No.

A. Okay.

Q. But on that subject, I do not think, as I understand it at least, you were not analyzing autopsy samples as a regular matter?

A. That is correct.

Q. Between July 1980 and March 1981, in any event?

A. Not as a regular matter, no.

Q. Were you doing it on occasion?

A. One was done, as I indicated before.

Q. Apart from that I take it you were not doing it?

A. No.

Q. On the matter of this Substance X about which we have heard considerable evidence, I take it from what you have said that your own



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observations at the Hospital for Sick Children basically support what we heard through Dr. Seccombe, that is the existence of some substance in the serum of young infants which apparently gives high levels of digoxin on RIA analysis. Is that fair?

A. Yes.

Q. You mentioned, I think, two things. First of all, the several tests that were done at the Hospital on children not receiving digoxin, which showed up these levels and, secondly, your own observations of children with high readings of digoxin who apparently showed no signs of toxicity?

A. And the literature relating to that phenomenon, yes.

Q. And the literature, which attributed it, as did you, to an apparent ability on the part of young infants to sustain relatively higher levels of digoxin than older children or adults?

A. Yes.

Q. So both those observations support, in your experience, the conclusions that Dr. Seccombe has reached?

A. Yes.

Q. Would you also agree with Dr. Seccombe that in light of his findings as



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confirmed really by you, there is some considerable doubt as to the reliability of digoxin RIA measurements in the serum of infant patients or at least certainly the infants under three months. Would you agree with his observation about that?

A. Yes, I think his observations, the observations in Washington, the observations of the Paediatric Clinical Chemistry Conference, the observations presented recently in Quebec City that he alluded to, I think all these would point to some caution in interpreting values at that particular age.

Q. Now, Doctor, you produced in the course of your evidence the extracts from the Residents' Handbook. I think you have the original. Can I see the original handbook for a moment?

A. Yes.

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EE-1

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Q. Do you have a copy of the
extract in front of you, Doctor? If not maybe we
can give you one.

A. Oh, okay.

Q. I gather from the preface
that you yourself are a member of the Handbook
Committee?

A. That's correct.

Q. And you have indicated that
you were responsible, at least in part, for the
chapter on biochemistry?

A. Yes.

Q. And this page 365 comes from
that chapter, is that right?

A. That's correct, yes.

Q. By the look of it, this
Handbook appears to be basically a Bible for
residents of the Hospital. Is that a fair
description of it?

A. You could use that expression,
yes.

Q. It is more or less intended
to be a guide to the residents in a variety of
situations and for a variety of procedures?

A. Yes.



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Q. Now, if you look at this page,
page 365 on Note 2, it says:

"Premature and low birth weight
infants appear to tolerate higher
levels but may not necessarily
benefit from them."

That's what you have just told us
about I believe, the observations in the literature
and the observations that you yourself have made,
is that right?

A. Yes.

Q. And would it be fair to say
that up until fairly recently at least that was
pretty much the traditional wisdom with respect to
infants and the treatment of digoxin, that is
they can tolerate higher levels than adults?

A. Yes, I think it is
controversial, that particular area.

Q. But certainly up until
relatively - it may be controversial now, but
certainly up until relatively recently it seemed to
be taken pretty much as gospel that the premature
and low birth weight infants could tolerate higher
levels?

A. Well, I did give the references



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to that, if anybody wants any further information.

Q. Yes.

A. They could always go to those references.

Q. But I take it you took them to be sufficiently established that you were prepared to include them in the Handbook at that time?

A. Yes.

Q. And I gather from what you've just said that certainly in light of Dr. Seccombe's findings that may not in fact be true, that they don't necessarily tolerate higher levels, in fact, they may simply have higher readings because of this Substance X, is that not so?

A. That would be one interpretation, yes.

Q. Certainly I take it a sufficiently plausible interpretation that you were prepared to agree with me a few moments ago that Dr. Seccombe's findings may explain that phenomenon?

A. Yes, I think until Substance X is isolated, purified and its pharmacological action, if any, has been established, it's pure speculation.



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Q. Well, let us put it this way.

Presumably in the next revision of the Resident's Handbook, it may well be that Note 2 is deleted, or at least substantially altered. Would that not be fair?

A. I don't know of any specific references that have totally contradicted that very cautious qualifying statement.

Q. What cautious qualifying statement is that?

A. That the situation appears to be a little equivocal and that they appear to tolerate higher levels, but they may not necessarily benefit from them.

Q. But surely what we have heard from both you and Dr. Seccombe is that it's not higher levels that they're tolerating, it is simply a certain level of digoxin and then another level of Substance X which is in effect cumulative?

A. But in many infants the level of Substance X I think Dr. Seccombe indicated was 0.2, 0.3.

Q. Yes.

A. Which is almost within the analytical error for measurement of most digoxin



EE-5

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Q. And in other infants I think
you said that it went as high as four?

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A. In the isolated cases, yes,
using the NML kit.

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Q. Well, shall we take it then
that this is going to remain the same, this Note 2
in the next edition or will it likely be changed,
do you think, based on what you know today?

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A. I see no real reason to change
that at this point. If the work is done, which
suggested that this is no longer valid, then
obviously that will have to be considered.

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Q. Well, just with reference to
that, you have above the notes, you have the values
of digoxin and you pointed out there I think that
the ranges shown there as far as you know are
adult ranges, is that right?

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A. These are, yes, in the American
Medical - Journal of the American Medical Association.

20

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Q. And the article that you
referred to, as far as you can tell, were for adult
ranges?

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A. Yes.

Q. And those ranges suggest that



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in the optimal range for adults would be .5 to 2.5 nanograms per millilitre, is that right?

A. This was my understanding at the time this was written, yes.

Q. And would it not be fair to say that a doctor reading this, a resident reading this would conclude that while .5 to 2.5 nanograms per millilitre may be optimal for an adult, a premature infant, or a low birth weight infant may well be able to tolerate higher levels than that? Wouldn't that be the logical inference from reading that?

A. Yes, but again, may not necessarily benefit from them. So, I would hope that these residents would go to the literature and read for themselves the information given there.

Q. I see. But certainly on a face reading of it, it would appear that the child can tolerate it without detrimental effects?

A. That may not necessarily benefit.

Q. All right. But there is no suggestion that there would be detrimental effects, is there?

A. Well, do you have some indication



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that there is?

Q. Well, I'm asking you. Is there any suggestion there that there is detrimental effects?

A. Above what level?

Q. Above the .5 to 2.5?

A. Yes. Well, in some studies Note 1, digoxin of above 2.5 or above 2 was potentially toxic.

Q. Yes.

A. Is that not clear?

Q. Well, what I'm asking you, Doctor - let's be clear that you understand my question.

A. Sure.

Q. This appears to indicate that .5 to 2.5 is the optimal range for therapeutic purposes. Am I right so far?

A. Yes, according to that reference.

Q. All right. And then Note 2 seems to suggest that premature and low birth weight infants can tolerate levels above those reference values that you have put in there, as I read it, without detrimental effect?



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A. This is what the literature
would suggest, but it is a controversial literature.

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Q. Well, the controversy, as far
as Note 2 seems to be concerned, is that it may not
necessarily be of benefit.

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A. But Note 1 -- you keep
skipping over Note 1 which says:

8

"Digoxin above 2.5 or above 2 was
potentially toxic."

9

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Q. Yes.

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A. Now, you know, would it be
possible for you to read this literature and then
come back and ask the questions perhaps?

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Q. No, I would rather do it just
now if you don't mind.

15

A. Okay.

16

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Q. What I'm asking you is, would
a resident reading this not conclude that a
premature or low birth weight infant could tolerate
higher levels?

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A. That may be the conclusion that
he might come to.

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Q. All right. What I'm asking
you now, today, is that, in light of all you
know and all the literature you've read and what we

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2 have heard from Dr. Seccombe, is that an appropriate
3 conclusion?

4 A. I think it is, yes.

5 Q. All right, thank you.

6 A. If I understand the question.

7 Q. If there is any doubt, let me
8 know and I will ask it again.

9 A. Are you saying, are the papers
10 in the literature which suggests that perhaps
11 infants can tolerate levels higher than 2.5 without
12 manifesting toxicity?

13 Q. I'm asking you, and I may have
14 to have the reporter read back my question, but I'm
15 asking you ---

16 THE COMMISSIONER: I think, if it
17 is of any help, from what I understand the question
18 to be is that in the Handbook, whenever it was
19 written, you said that premature and low birth
20 weight infants appear to tolerate higher levels?

21 THE WITNESS: Yes.

22 THE COMMISSIONER: Now, is there a
23 possibility that it's not that they tolerate higher
24 levels but that they just have a reading which is
25 higher for the same amount of digoxin. That
question was probably put even worse than has been



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put before, but that's all he's asking. I'm not too
sure that it really matters what the answer is
because we've heard the evidence, you've heard the
evidence.

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THE WITNESS: Yes.

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THE COMMISSIONER: And if Dr.

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Seccombe was to be accepted, or his evidence to be
accepted, there apparently is some kind of substance
which distorts the reading, at least under the RIA
method.

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THE WITNESS: Yes, I believe that's
the case.

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THE COMMISSIONER: So, that may be
the answer. That's all that I think Mr. Strathy
is trying to get to you. Now, if you were to re-word
this, premature and low birth weight infants may be
able to tolerate higher levels and may also record
higher levels than actually exist because of some
substance in their make-up. Would you accept that
as a proper statement?

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THE WITNESS: Sure, yes.

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THE COMMISSIONER: Well, that's the
kind of amendment Mr. Strathy is trying to get you
to agree to.

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THE WITNESS: Okay.

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MR. STRATHY: Q.. Would you go along with the Commissioner's amendment?

A. In the light of present knowledge.

THE COMMISSIONER: You don't have to, you know!

THE WITNESS: The matter is exceeding ---

THE COMMISSIONER: My qualifications are nil, but that's what the evidence seems to disclose.

THE WITNESS: The matter is exceedingly complex. Digoxin readings with some kits may measure Substance X plus digoxin. The literature cited in 1977 and '78 before and since, without knowing the exact specificity of the digoxin method in relation to digoxin and Substance X, without knowing exactly what those specificities are, it is almost impossible to read the literature in retrospect because of this simple point.

THE COMMISSIONER: Yes, all right.

MR. STRATHY: Q. Would you not go so far as to agree that perhaps in light of what we now know about Substance X, it might be advisable to include some further qualifies into Note 2.



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Would you go as far as that?

A. If the overall editor of the Residents' Handbook at the next edition will permit me to expand on these already lengthy notes, then perhaps that might be included.

Q. I think that's probably as far as I'm likely to take you at this point.

Mr. Commissioner, I'm going to be a while further. I don't know what your plans are.

THE COMMISSIONER: Well, we can rise now. I wonder if we could take a poll? Mr. Hunt, how long will you be, do you think?

MR. HUNT: I would think ten minutes.

THE COMMISSIONER: Mr. Buhr?

MR. BUHR: I don't have any questions.

THE COMMISSIONER: Ms. Goodman?

MS. GOODMAN: No questions.

THE COMMISSIONER: Mr. Young?

MR. YOUNG: I don't have any questions.

THE COMMISSIONER: Mr. Ortved?

MR. ORTVED: No questions.

THE COMMISSIONER: Mr. Labow?

MR. LABOW: No questions.

THE COMMISSIONER: Mr. Tobias?

MR. TOBIAS: About ten minutes, Mr.



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Commissioner.

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THE COMMISSIONER: Mr. Olah?

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MR. OLAH: No questions, Mr.

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Commissioner.

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THE COMMISSIONER: Well, I think we
might get through this afternoon, I don't know.

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Would that be convenient to you, Mr. Lamek, or Ms.

8

Cronk, if we could get finished this afternoon?

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MS. CRONK: Yes.

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THE COMMISSIONER: Oh, I'm sorry,
I forgot about Mr. Scott whose got a large part to
play in this.

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MR. SCOTT: If Mr. Strathy keeps on
the straight and narrow, no questions.

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MR. STRATHY: I'll do my best.

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THE COMMISSIONER: Ms. Cronk, do
you have any re-examination?

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MS. CRONK: A very brief re-
examination.

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THE COMMISSIONER: Well, we might
make it this afternoon. Well, let's rise for, what,
what do you want, 15 minutes or 10?

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MS. CRONK: Ten.

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MR. STRATHY: I think I may be a
while, so, the shorter the better if you're hoping

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to finish this afternoon.

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THE COMMISSIONER: The only problem is, if we say ten minutes and people then take 15. However, as long as you only take ten minutes, then we're okay.

MR. STRATHY: No. Well, I'm saying I may be a while.

THE COMMISSIONER: You and the witness ten minutes and I don't really care how long the others take.

--- Short Recess.



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--- on resuming at 3:55 p.m.

THE COMMISSIONER: Mr. Strathy.

MR. STRATHY: Thank you, Mr.

Commissioner.

Q. Doctor, referring back to the Resident's Handbook page that you have in front of you, page 365, at the very top under "Digoxin", there is a reference that says:

"Note. This assay cannot be done on blood of patients treated with digitoxin."

Can you explain that reference to us, please?

A. Because of the cross-reaction of digitoxin, only about 1 per cent of the digitoxin compared with digoxin would cross-react in our assay, so it is not really recommended for patients who are being treated with digitoxin.

I don't think digitoxin is used in the Hospital For Sick Children. It is just that this book is sometimes used outside and, although it is not very commonly used, I think that qualifier has to be given.

Q. So, it is really not that it cannot be done; it is just that, if it is done on



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blood of patients treated with digitoxin, you won't get an accurate reading?

A. Yes.

Q. Is it fair to say that the result you would get would be about 1/1000 of the actual reading?

A. I think it would probably be of the order of 1/100 or 2/100. There are specific digitoxin kits available on the market if anybody wishes to use those.

Q. That is what I was wondering about.

Going down to Note 3, which we haven't discussed and which I think I understand, am I correct in understanding that where the child is either under three months of life or is suffering from renal failure, the body is not able to clear the digoxin out as efficiently as it might otherwise be able to do?

A. Yes.

Q. And the effect of that is that you may have higher levels of digoxin in children with either immature renal appearance or with renal disease?

A. Yes.



Ellis
cr.ex. (Strathy)

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Q. In Note 4, you say:

"In adults, hypomagnesemia or hyperkalemia may predispose to digoxin toxicity even when the serum digoxin is optimal."

Is that finding borne out with respect to infants as well?

A. As far as I am aware, it is, but you would be better to ask a physician about that. The particular reference that I gave there in the Quarterly Journal of Medicine --

Q. Yes.

A. -- relates to adults.

Q. Can you briefly, in words that we might understand, tell us what hypomagnesemia is and what the other words mean.

A. This is a low magnesium level, hypomagnesemia or low level in the blood serum or plasma.

Q. So, "hypo" means low?

A. Yes. Hypo or hyperkalemia, was that the other?

Q. Yes.

A. This relates to the potassium level in the blood or plasma or serum. "hypo" being



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low and "hyper" being high.

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Q. So, when those conditions exist, you may have the symptoms of toxicity without the actual digoxin count reflecting toxicity?

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A. The symptoms shown by the patient may be modulated for a particular digoxin level by these alterations of plasma electrolytes.

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Q. Conditions may be..., excuse me?

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A. May be moderated, may be varied, may be affected by these different substances.

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Q. So, you have some of the symptoms of toxicity without necessarily the serum levels which would reflect toxicity?

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A. Or vice versa.

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Q. Now, I want to refer you to another page in the Handbook, and unfortunately I don't have it copied, but my friend, Miss Cronk, has an extra copy.

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I'm sorry, Mr. Commissioner, I don't have a copy for you. I just have this copy.

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It is at page 200. However, perhaps we can have a copy made of it at some later point.

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Page 200 is under the section dealing with "Cardiology".

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Did you have any responsibility at all



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for this section, doctor?

A. No, I didn't.

Q. If you would look at page 201 under Heading No. 4, it is talking about the treatment of congestive heart failure, and it says, first of all, "Bedrest"; secondly, "Oxygen as required"; thirdly, "Diuretics".

Stopping there for a moment, as I understand it, renal failure is a common symptom of congestive heart failure and, in those cases, the treatment with diuretics is often prescribed.

Does your knowledge permit you to go that far or not?

A. There is a fluid overload and, so, diuretics are prescribed.

Q. In congestive heart failure?

A. Yes. In certain types of congestive heart failure.

Q. And carrying on at page 201 under Heading No. 4, "Digoxin", it talks about the administration of digoxin to patients with congestive heart failure.

If you look at the bottom under 4E, it says:

"Chronic renal disease. Use dose



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according to serum, creatinine or
BUN levels. Monitor dose by serum
digoxin levels (therapeutic levels
equals 0.8 to 1.8 nanograms per ml)."

Do I understand that to mean that
the therapeutic level of digoxin in the patient would
be in that range?

A. Yes. The 0.8 to 1.8 nanograms
per ml is a figure that we initially used, certainly
when I came to the Hospital in 1976.

Until you mentioned it, I was not
aware that, on page 201, this information was given.
This particular section was prepared by probably
a Cardiology Fellow, I would guess.

Q. I'm sorry, you were not aware
of that?

A. No, I wasn't, no.

Q. Just a second now, I have your
book.

A. I don't think I was aware.

Q. I think -- I don't know if
that is your handwriting or not. It says, "See
Biochem."

A. Oh, yes. Okay.

Q. Is that your handwriting?



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A. I must have been aware of it at some time.

Q. Dealing with this sub-E, am I right in understanding that the levels there, .8 to 1.8, are the therapeutic range being indicated by the authors of this section pertaining to treatment of patients with congestive heart failure?

A. Yes.

Q. And we can see then that that range is somewhat different than the range that you have indicated on your notes on page 365; is that right?

A. Yes. I think this ties in with Note 1 on page 365:

"The serum concentration over which toxicity becomes more likely is not clearly defined and varies between individuals. In some studies, digoxin above 2.5 or 2 nanograms per ml was potentially toxic."

I suppose we could add to that that there are some studies that would indicate that levels of 1.8 nanograms per ml are potentially toxic.

Q. Well, this note at page 201 doesn't include any qualification. It suggests that



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the therapeutic level is .8 to 1.8, which even 1.8 is below the lowest range that is suggested on page 365, isn't that correct?

A. The .8 is...?

Q. 1.8 is below the lowest range that you suggest at page 365.

A. Yes. 1.8 is below 2.0, yes.

Q. Which is the lowest range that is even remotely suggested at page 365.

A. Correct.

Q. So, apparently at least, there is some inconsistency between what is shown in the congestive heart failure section and what is shown in the biochemistry section --

A. Yes.

Q. -- as to the appropriate therapeutic range?

Mr. Commissioner, can I undertake to have a copy of this made and file that page as the next exhibit, please?

THE COMMISSIONER: Yes, we will do that tomorrow.

MR. STRATHY: I will see if I can get somebody to do it right now.

Q. Now that I have given away my



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Handbook, I may have run out of questions!

A. I think it was my Handbook,
wasn't it?

Q. Let me take Miss Cronk's.
There is also a section at page 204
which is entitled "Routine Treatment of Digitalis
Poisoning".

I want to ask you whether you are
familiar with this portion of the Handbook dealing
with treatment of digitalis poisoning.

A. I don't think I am, no.

Q. Have you ever had occasion
to read it or see it before?

A. I don't know whether I have
written any comments on my copy on this occasion.

What specifically would you like me
to refer to?

Q. I am just wondering whether
you have read it. I am going to refer you to one
or two sections in a moment.

A. I don't know whether I have
read through the whole Handbook.

Q. Can you assist me on this?
Is the reason for the inclusion of this particular
section the possibility that a child may come across



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a parent's or grandparent's digitalis and accidentally swallow it? Is that why it is included?

A. Yes. This has happened on some occasions.

Q. So, it is dealt with as an example of one of the poisons that a child may take --

A. Yes.

Q. -- by accident from time to time?

A. Yes.

Q. That is why it is included in the Handbook, is that it?

A. Yes. There was a case very recently, in fact.

Q. In your Hospital?

A. Yes.

Q. It says, under this note:

"Symptoms occur 30 minutes to six hours after ingestion, usually nausea and vomiting initially."

Do you know enough about the symptoms of digitalis poisoning to be able to say whether those are the accurate timeframes for the occurrence of poisoning symptoms?

A. No.



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Q. Do you know enough about the symptoms to be able to say what the symptoms are?

A. Of the vomiting?

Q. And nausea?

A. And nausea. I understand that is some of the symptoms that may -- yes.

Q. I would like to ask if Exhibit 14 can be put in front of you, please. That is the materials from Antibodies Incorporated.

You mentioned this morning in the course of cross-examination, I believe, that there were two types of interferents which might create a misleading digoxin level. I think you called one analytical interference and the other physiological interference.

Do you recall your evidence about that this morning?

A. Yes. I don't think I said "misleading".

Q. That is my word, I suppose. What word would you use?

A. Well, I don't know.

Q. What is the result? Is the result of those interferents not to produce readings which are inaccurate or do not accurately reflect



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the true digoxin in the system?

A. It is my understanding that certain drugs that may be co-administered with digoxin may affect the handling by the body of digoxin and cause a true elevation of digoxin in the patient's plasma. That is one type.

Q. That is the physiological type, is it not?

A. Yes.

Q. But there is also another type that you mentioned, and that is what I think you called the analytical situation.

A. Yes.

Q. Where, in effect, you are reading digitoxin or things like digoxin rather than digoxin?

A. Yes.

Q. The result of either one of those "interferents" is to produce, if you will, inaccurate readings if you are reading for digoxin?

A. No. I think, in the first case, you are getting a n accurate digoxin reading. It is just that it is raised from perhaps a normal level to perhaps an abnormal level as a result of impaired excretion, perhaps brought on by this other



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Q. All right. That's a fair point. So that, really, in the first case that you are talking about, the physiological situation, the physiological interferent, what you are doing, in effect, is boosting the digoxin level by the use of some other drug?

A. Yes, or preventing its excretion by the body.

Q. Are you able to tell us what type of drugs have that physiological effect?

A. I think that quinidine alters the distribution of digoxin by the body.



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Q. And that in fact is mentioned
in your requisition form?

A. Yes.

Q. Anything else?

A. I think, the aldactone.

Q. Aldactone, spironolactone?

A. That competes with digoxin for
excretion but it would be better to clarify this with
a pharmacologist.

Q. Are there any drugs, offhand,
that you are able to think of now that have that
effect or not, other than you have mentioned?

A. Pardon?

Q. Other than the quinidine,
aldactone and spironolactone, is there anything else
you can tell us in the way of drugs that have that
effect?

A. Not offhand, but there are some.
I think perhaps amiodarone, does that not interfere
in that way?

Q. I think that has been mentioned
as one of the drugs.

A. There are a number of them, I
believe.

Q. In terms of the analytical



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interference, am I right that there you are talking
about things like digitoxin and some of the other
digitalis derivatives?

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A. Yes.

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Q. Or compounds that are structurally
similar to digoxin?

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A. Yes.

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Q. Now would I not be correct in
understanding that you as a Biochemist, involved in
the analysis of digoxin, would be very interested in
knowing what type of drugs react with a particular
antibody for digoxin? As a consumer, would that not
be of considerable concern to you?

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A. Yes, particularly when setting
up a method from scratch.

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Q. All right. As I understand
your evidence, you made inquiries of Antibodies Inc.,
to try and find out just that, what sort of drugs
did react with their anti-serum?

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A. Yes.

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Q. And in fact the Commissioner
asked you about this question last day when you
pointed out specificity related only to those items
which apparently had a very low reaction and the
Commissioner queried you as to what about the other



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things that might have a higher reaction and you said that you raised that with Antibodies Inc. and they were not able to help you?

A. Yes.

Q. Does that not strike you as incredible, that a manufacturer of a serum like this cannot tell you, the consumer, in this day of consumerism, what sort of things react with its product? It strikes me, not knowing a lot about your business, but it strikes me, frankly, as incredible that they could not tell you.

A. Basically I think, as I indicated before, there is no requirement in law for them to retain all that information, according to the Food and Drug Administration, from what I was advised.

Q. Whether there is or is not a legal requirement, surely as a manufacturer, aware that it might well be faced with an inquiry from potential users, surely you would think at least that the manufacturer would know what its anti-serum would react to?

A. You would hope that when they were initially obtaining the anti-serum they would have subjected it to an extensive evaluation.

Q. And they would keep a record



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of those things so they would know in response to
future inquiries.

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A. I think that would be helpful
for them to do that, yes.

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Q. So, did it not surprise you at
the time that they were not able to tell you the
information?

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A. Surprised - what do you mean by
surprised?

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Q. I guess you phoned them hoping -
you did telephone them?

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A. Yes, I phoned them asking for
this information, a nice list, giving all this detail
and they did not provide me with one. The only thing
they were prepared to advise me on was they wrote me
a letter to indicate that it was highly specific for
digoxin and cross-reaction with digitoxin is less than
2 per cent of the 50 per cent inhibition level, and
they expressed confidence that the antibody specificity
would not substantially contribute to any error in
the measurement of serum digoxin levels.

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Q. Could I see the letter?

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A. Yes. And this was about 19 -
was it '69 - or 1980.

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Q. December 31, 1981.

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A. 1981, okay. So this, plus the fact that we had been using the assay, as far as I was concerned successfully, since 1975, to my knowledge without any major problems, I was not too concerned about that.

Q Did you ask them about the reference in Exhibit 14 on digoxin which you read as digitoxin, did you ask them to clarify that, if what they meant on Exhibit 14 was digitoxin?

A. No, Exhibit 14 is actually material that I obtained from Dr. Cherian on the 23rd of June of this year, so I was not in possession of that information at this time - at the time of December 31st, 1981.

Q I see. So you are reading Exhibit 14 in light of what you were told in December of 1981?

A. Yes.

Q And you have not taken up this question of whether digoxin should be digitoxin. You have not taken that up with the people at Antibodies Inc.?

A. No, I have not, no, but in the light of their letter it would seem highly likely.

Q That is your interpretation of



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what they say in the letter?

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A. Yes. They say the cross-reaction is less than 2 per cent. The cross-reaction for digoxin for digoxin antibody has to be 100 per cent.

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Q. Right. I have page 200, Mr. Commissioner, of the handbook. Perhaps that could be marked as the next exhibit. I do not have copies for all counsel so perhaps we could have copies made at some future time.

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THE COMMISSIONER: Page 22, is it?

MR. STRATHY: Pages 200 and 201.

THE COMMISSIONER: I am just trying to find a title for it that is all.

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--- EXHIBIT NO. 18: Pages 200 and 201 of the Residents Handbook.

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MR. STRATHY: Q. Lastly, if you could take a look at Exhibit 17, please, Dr. Ellis, that is the article from the Journal of American Medical Association.

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THE COMMISSIONER: I don't think I have that.

MR. STRATHY: I am afraid you are going to have to give us a little bit of assistance in one area. That is with respect to the reference in the headnote or summary at the very beginning of the article where it talks about recent radioisotopes



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on board. I am afraid I did not quite understand your explanation of what that means.

A. In the investigation of certain children in addition to performing X-rays of various organs on the children it is sometimes necessary to administer a radioisotope which is accumulated by various organs and tissues in the body. As a result of this accumulation, various pictures can be taken which are helpful in diagnosing certain malformations of that particular organ.

Q. May I stop you there for a moment. Is there a name for that procedure?

A. It is usually called a scan, a radioisotope scan of some sort.

Q. I am sorry I interrupted you.

A. Now, if a child has received the radioisotope and the scan has perhaps been performed or is about to be performed and a blood sample is taken at that time, the blood may contain a certain amount of the radioisotope, and it is always possible that that radioisotope might interfere in some way with the assay.

Q. In what way would it interfere?

A. It would conceivably produce inadvertently unexpectedly low results, I would think.



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Q. Unexpectedly low?

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A. Yes, but it would depend on

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the actual isotope that has been administered and

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on the characteristics of the isotope and the organic

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material in which the isotope is incorporated, whether

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it bound charcoal or whether it remained free,

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for example, and which assay was being used and

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whether the gamma counter was selected for that

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particular isotope.

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Q. But in any event the effect

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would be to produce misleadingly low digoxin levels?

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A. It could well be to produce

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misleadingly low or inappropriate digoxin levels.

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Q. The isotopes that are used in

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that procedure very often have a very short half-life

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which means that they deteriorate very quickly, they

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break down very quickly. They are also excreted from

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the body quite quickly so the chance of actually

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getting a sample, analyzing it and repeatedly

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analyzing it over several days and getting a

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consistent answer, are really quite remote; but this

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should always be considered with any radioisotope

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procedure.

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Q. All right, thank you. Thank

you for answering my questions.

MR. STRATHY: I have no further



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questions. The only observation I might make, Mr. Commissioner, is that it would be a pity if the day went by and Miss Cronk's art work was not filed as an exhibit. Perhaps I can leave it to her --

MS. CRONK: I'm not sure that is a pity at all, Mr. Commissioner.

MR. STRATHY: They make the interpretation of the transcript more intelligible, but I will leave that up to her.

MS. CRONK: I do have a copy of it, Mr. Commissioner, if Mr. Strathy would like it marked, that is fine.

THE COMMISSIONER: Apparently he has left it up to you so you can consider that, whether you want to put it in or not.

Mr. Hunt.

CROSS-EXAMINATION BY MR. HUNT:

Q. Dr. Ellis, you are a Clinical Biochemist, is that correct?

A. Yes.

Q. And you have no experience whatsoever in forensic toxicology?

A. That is correct.

Q. And you would agree with me that there is a significant difference between the



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two fields of chemistry, that is yours and forensic toxicology?

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A. A radioisotope performed with a kit in two different laboratories may be really quite similar but the objectives of the two laboratories are quite different.

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Q. From what I have been able to absorb over the last several weeks, a forensic toxicologist is concerned, in addition to and perhaps prior to being concerned with levels of the drug, he is concerned with specificity, that is, identifying the presence of a particular drug in a sample?

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A. We are also concerned with specificity, too.

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Q. Would it not be fair to say, sir, that in most cases you are aware of what drug it is that you are analyzing, and the question is what is the level that is found in the sample?

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A. I would hope we measure - you know, I would hope that we were measuring the drug that we thought we were measuring, if that was your question.



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Q. Well, sir, when the request comes to you to do an analysis of a sample, you know at that point in time what it is you're looking for, you are attempting to establish a level of that particular drug?

A. Yes.

Q. The forensic toxicologist on the other hand may well be looking for a drug in a sample at the outset he has no knowledge or little knowledge and then seeks to establish a level of it once identified?

A. Yes. There are some clinical chemists who would have the similar problem to the forensic toxicologist, an overdose case where it isn't clear what drug has been given. Those clinical chemists may be called upon to analyze for several drugs and do various drugs screens but I personally don't do that.

Q. In the case of clinical chemists that are called upon to examine samples in connection with overdose, the samples they would be examining by and large would be from a living person?

A. Not necessarily but they may well be.

Q. In most cases I suggest they



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would be.

A. Yes.

Q. And in the cases where they aren't, I suggest they would be samples that would be taken from the body in a period of 12 to 24, perhaps 36 hours afterwards?

A. I think this would usually be the case, yes.

Q. And a clinical chemist would not normally be called upon to analyze putrified samples?

A. Definitely not.

Q. Nor hemolyzed blood?

A. Hemolyzed blood?

Q. Hemolyzed blood.

A. Occasionally hemolyzed blood is submitted for analysis, depending on the test that's required of that blood, it may or may not interfere.

Q. I take it that would be rare though?

A. No, hemolysis during the collection of a blood sample is fairly common.

Q. All right. Would it be fair that samples of that type of blood ---



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THE COMMISSIONER: Excuse me, what
is this kind of blood?

THE WITNESS: Oh, hemolysis. It
means that the red cell is slightly broken down, so,
an impure sample of plasma or serum is obtained
and that hemolysis may occur as a result of taking
the blood sample under difficult conditions.

MR. HUNT: Q. It may also occur
as the cells in the body begin to break down after
death?

A. Yes.

Q. Would it be fair to say that
generally the clinical chemist is involved with
analyzing samples that come from living beings as
opposed to post mortem samples?

A. Yes.

Q. And the reverse is true of
the forensic toxicologist, or often they are examining
samples that come from deceased than they are samples
that come from living beings?

A. Well, they would quite often
analyze alcohol from subjects with impaired driving
perhaps and this kind of thing.

Q. Well, let's restrict it to
samples of bodily tissues and blood. In that



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context, would it not be fair to say that the forensic toxicologist is normally examining samples of those substances that come from the deceased?

A. You exclude blood alcohol?

Q. All right, we'll exclude the case of blood alcohol.

A. Yes, I think perhaps a forensic toxicologist, you could ask him exactly what he does.

Q. Well, I'm sure we'll have more than testifying, sir, and I will.

The bottom line, if I can put it that way, sir, is that the methodology that is used by a clinical chemist requires experience, the development of it requires experience in dealing with and manipulating the types of samples that a clinical chemist normally deals with. Do you follow my question?

A. We normally analyze substances that we normally analyze.

Q. In order to become a good clinical chemist, sir, one has to have experience in dealing with those substances that you are going to be analyzing time and time again?

A. Yes.



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Q. And you build your methodology for analyzing them around the properties of those samples?

A. Yes.

Q. And by and large those samples are ante mortem samples that come from living human beings?

A. Yes, in clinical biochemistry.

Q. And would you agree with me that a forensic toxicologist, in order to become good, requires experience in dealing with and manipulating those samples that he is going to be working with on a day to day basis?

A. Sure, yes.

Q. And he builds his methodology around the properties of those samples which by and large will be post mortem samples?

A. He would hopefully derive, you know, an appropriate methodology for the sample that he's dealing with.

Q. And the formulation of the different approach is going to require the experience of the different type of chemist in dealing with those samples?

A. Yes.



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Q. And you, sir, as a clinical chemist don't put yourself forward as being in a position to comment at all upon the appropriateness of the methodology that a forensic toxicologist may develop?

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A. How do you mean?

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Q. Well, I suggest, sir, that you're not in a position as a result of your own particular experience as a clinical chemist to comment at all upon the appropriateness of methodology that a forensic toxicologist may develop to deal with a situation that is within his normal activity?

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A. Are you asking me whether I'm familiar with a lot of analytical techniques, some of which may be used by a forensic toxicologist?

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Q. No, sir, I'm suggesting to you that you as a result of your particular experience as a clinical biochemist are not in a position to comment at all upon the appropriateness of methodology that a forensic toxicologist may develop in order to meet a particular situation within his proper sphere of activity?

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A. Well, I may be in a position to comment on the analytical techniques that are



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being used if required to do so or requested to do
so. If we are talking about radioimmunoassay for
example, then I have probably as much experience
as many forensic toxicologists in radioimmunoassay;
not of autopsy samples or not of tissues.

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Q. Well, sir, unless I mistook
an answer that you gave last week, I was under the
impression that you don't ---

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MR. SCOTT: Page, please.

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MR. HUNT: 924.

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Q. You were asked, sir, at about
line 14:

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"Q. I take it then you are not in a
position, given your lack of experi-
ence in a forensic as opposed to a
clinical setting, to provide us with
your views as to what might or might
not be appropriate method of testing
for digoxin in a forensic situation?

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A. Yes."

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A. Yes.

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Q. That essentially, sir, is what
I am putting to you, that you, because of your own
particular clinical experience are not putting your-
self forward as an expert who is in a position to



comment on the appropriateness of a methodology that a forensic toxicologist may have developed in order to test for digoxin in a forensic setting.

A. Yes, sure. I don't profess to be a forensic toxicologist. Is that the question you're asking?

Q. No, sir. I will go through it once more. The question specifically that I'm asking is, I am suggesting to you that it's because of your own particular experience as a clinical chemist that you are not putting yourself forward as an expert at all on the methodology that a forensic toxicologist may develop in order to test for digoxin in a forensic situation. That's the question.

A. I'm not in a position to comment on immunoassays or high performance liquid chromatography.

Q. Well, the question that I'm asking is whether you are -- I am suggesting to you that you are not, sir, sufficiently qualified as a result of your inexperience in dealing with forensic chemistry to comment at all with respect to the appropriateness of methodology that may be developed by a forensic toxicologist.

A. Well, that may be your opinion, yes.



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Q. Well, I'm suggesting to you,
sir, that isn't that a fact?

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A. Well, I'm familiar with a
number of analytical techniques, some of which may
be used by clinical chemists and some of which may
be used by forensic toxicologists. If you're asking
me whether I'm familiar with those techniques, I'm
indicating that I am.

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Q. Well, would you not agree with
me, sir, that it takes a little bit more than being
familiar with techniques to comment with authority
with respect to the appropriateness of the use of
those techniques in a situation in a forensic
setting?

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A. I think in both instances
good analytical technique would be required. And,
you know, one would hope that it would have been
applied in both situations.

Q. Well, I would think that goes
without saying, sir, but the question is a little
more specific than that, or my suggestion to you is
a little more specific than that and, that is, is
that because of the difference between the two
fields of chemistry, that is, clinical biochemistry
and forensic toxicology, that the adaptation that



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might be used by a forensic toxicologist with respect to a certain methodology really distinguishes itself from the type of methodology that you yourself might use in a clinical setting that you are not in a position really to comment in an authoritative way with respect to that methodology or the appropriateness of it?

A. If it will make you happy for me to say yes at this point, we could say yes and continue. I think I have elaborated my qualifications to you on your rather leading question and I stick by that. If you are asking me about analysis, then I have a lot of experience in analysis; if you're asking about forensic toxicology, then I have virtually zero experience in that, other than reading a few forensic toxicology papers. Is that okay?

Q. You would agree with me that other than reading the forensic toxicology papers, the absence of experience in dealing with chemistry in a forensic setting really prohibits you from commenting with authority on that type of chemical analysis.

A. Prohibits me from commenting with authority?

Q. Yes.



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A. In a forensic sense?

Q. Yes.

A. If that will -- yes, okay.

Q. You don't have to do anything
to make me happy.

MR. SCOTT: Well, Mr. Commissioner,
isn't the question whether a forensic chemist will
from time to time use RIA for digoxin and whether
a biochemist will use RIA for digoxin and is there
any difference between the two techniques?

THE COMMISSIONER: That's one of
the questions.

MR. SCOTT: Perhaps one of my
friends will save me the trouble of putting that
question because the answer is yes.

MS. CRONK: That is the question.

MR. HUNT: Well, I enjoy
Mr. Scott's cross-examination so much I'm going to
leave that question for him to put to the witness,
Mr. Commissioner.

Q. Sir, if a clinical biochemist
purports to be able to speak with authority with
respect to matters that involve forensic toxicology,
would it not be prudent for us to enquire into that
particular experience in dealing in a forensic setting?



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A. Yes, sure, if he went as far as that, yes.

Q. Now, sir, in the period of review, which is July, 1980 through to March, 1981, can you tell me whether or not there was a formal or an informal arrangement with other hospitals whereby the Hospital for Sick Children had testing for digoxin done elsewhere?

A. I'm only aware of the one instance that I previously referred to in respect of - was it Estrella or was it Pacsia. I guess we'll come on to this.

Q. Yes, I don't want to get specific about it but I'm just wondering whether or not this was a formalized arrangement between the Hospital for Sick Children and Mount Sinai or other hospitals.

A. I'm not aware of any such formalized arrangement for the exchange of a large number of samples between the two hospitals. There are, as I indicated, at the Preliminary Inquiry, several instances where we have problems with a particular assay, digoxin, DHA, sulphate and thyroxine and we might exchange samples with that hospital on an informal basis and obtain the answers



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that they had obtained with their method and
compare them with the answers that we had obtained
by our method.

Q. And insofar as digoxin testing
is concerned, you are aware of only the one instance
that's been referred to by yourself at the
Preliminary Hearing?

A. Yes. I think I may have
indicated that in 1972 I think all samples were
sent over to - or was it '73 - all samples were
sent over to Mount Sinai before they were actually
done at the Hospital for Sick Children starting in
1975.



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Q. And was there any written record kept with respect to samples that were tested elsewhere?

A. Not on any formal basis to my knowledge. If there is any evidence in the books that are probably currently in police hands as exhibits I would be grateful if anybody could point that specific instance out to me so I could follow it up if necessary. I don't know of any formal arrangement that has been made.

Q. Where this occurred, who would be responsible for making that decision in the request of the other hospital.

A. It would - probably I would phone my counterpart at Mount Sinai, or I would phone my counterpart at Toronto General and say that we were having a possible problem with an assay and would they analyze some serums for us. When the count situation occurred they would contact me.

Q. Would the hospital then receive a report from the hospital that performed the tests?

A. It would probably be a very informal arrangement, perhaps a bit of paper, you know, one of us might go across to the hospital on



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2 some occasions and discuss the results with our
3 counterparts or they may come over to us.

4 Q. Would you normally receive
5 any kind of formal reports such as you might prepare
6 yourself when you are asked to perform an analysis?

7 A. No. It wouldn't usually go
8 through any kind of a formal procedure. Simply
9 because that sample received at the front desk of
10 the hospital laboratory would have to be documented
11 and appropriate billing would have to be prepared
12 and so it is usually on an informal arrangement.

13 Q. What would happen to any kind
14 of written piece of paper that might be returned to
15 you following the analysis?

16 A. Well, that might be filed, I
17 would hope that would be filed.

18 Q. Filed with the patient's chart?

19 A. With the patient's chart?

20 Oh, no.

21 Q. Would that not possibly be
22 something that is relevant to a particular patient?

23 A. No, I mentioned informal
24 arrangements. So it would be very unwise to file
25 let's say two answers for the same serum, the same
test from different hospitals, this would cause



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confusion.

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Q. Perhaps because of the

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difference in the manner of testing?

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A. The difference in methodology

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I would expect that to give some difference in
result.

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MR. HUNT: All right, thank you.

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THE COMMISSIONER: Dr. Ellis, will

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you be available tomorrow?

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THE WITNESS: Yes.

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THE COMMISSIONER: I was thinking

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we might rise now but if anyone has any urgent
desire to conduct a short cross-examination we
can do that.

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MR. TOBIAS: Mr. Commissioner, I
intend to be very brief, probably finished in five
minutes.

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THE COMMISSIONER: Nobody has

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succeeded in doing that so far but I will give you
a chance.

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MR. TOBIAS: I am very confident

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I can get in under five minutes and I am sure
Dr. Ellis would prefer to be rid of me today.

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THE COMMISSIONER: Yes, well,

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I won't ask him that question.

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MS. CRONK: Mr. Commissioner,
perhaps before you make that final determination
I will have re-examination of approximately 10 to
15 minutes. I don't know if you wish to ---

THE COMMISSIONER: Yes, the
final determination has only to do with Mr. Tobias,
it has not to do with anybody else. No, we have
lots more before we come to you.

MS. CRONK: I'm sorry,
Mr. Commissioner, I thought from the early indication
Mr. Tobias was the last who intended to cross-examine
this witness and the hope was he might be free this
evening. Mr. Tobias will be finished this evening,
that is all. Yes, all right.

CROSS-EXAMINATION BY MR. TOBIAS:

Q. Dr. Ellis, you have indicated
several times that you were present during the
evidence of Mr. Cimbura?

A. Yes.

Q. I don't know if you will recall
but there was some discussion during the giving
of that evidence between the difference involved,
or the distinction I think is a fairer word in
attaining the measurement in a sample and interpreting
that measurement.



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A. Yes.

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Q. I believe that it is fair to paraphrase Mr. Cimbura's evidence to the extent that he was saying that he was satisfied that the measurements that he took were accurate and that we would have to direct our minds to other witnesses with respect to specific interpretation of those measurements. Do you agree in general with that statement by him?

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A. I don't recall him making that specific statement, but that seems a reasonable statement to make.

Q. Now, in cross-examination by Miss Symes earlier today, you indicated that you agreed with her that to your knowledge the kits, the various kits that are used in the RIA technique were really designed to test ante mortem levels of digoxin on serum, or plasma. I take it that you are satisfied that it was not part of the original scheme, or design in developing those kits to use them on post mortem tissue, is that correct?

A. I think most of them were designed for plasma.

Q. All right. Now, would you agree with me that with respect to the using of



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those kits ---

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THE COMMISSIONER: Plasma is an
ante mortem substance, is it, can you not get plasma
after death?

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THE WITNESS: Yes, plasma or serum
usually taken for therapeutic drug monitoring
purposes.

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MR. TOBIAS: Q. You said it was
designed to use on plasma; plasma, does it not exist
after death?

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THE COMMISSIONER: Perhaps you
can help me, and I won't count this against your
five minutes.

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MR. TOBIAS: That is quite all
right, Mr. Commissioner, you have my indulgence.

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THE COMMISSIONER: You mean that
they were designed - I take it, I hope I am not
leading you too much but I would think most of
these kits would be designed in any event for ante
mortem use.

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THE WITNESS: Yes.

THE COMMISSIONER: Is there any
suggestion in any of the kits that can be used post
mortem, what is the basis, if there is any basis,
for saying they shouldn't be used post mortem?



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THE WITNESS: I don't know of any specific indications as to why they shouldn't be used post mortem. I know of no kit that specifically excludes that possibility as a specific exclusion for its use. There are substances I guess in plasma and in blood that perhaps as a result of some decomposition might interfere with the test. I don't think that the kit manufacturers would test for this, so it would have to be used with great caution.

THE COMMISSIONER: It would have to be ---

THE WITNESS: Be used with a lot of caution and a lot of checks.

MR. TOBIAS: Q. Dr. Ellis, are you specifically aware of any problem that would rule out the possibility of making certain adaptations to the method to allow one to obtain readings, using the RIA method on post mortem tissue, or post mortem serum?

A. Am I aware of any?

Q. Of any specific problems which would rule out the possibility of allowing one to make appropriate adaptations to obtain readings using the RIA technique on post mortem tissue of



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serum samples?

A. Not rule out the possibility, no, but would necessitate perhaps a modified procedure being used such as perhaps an extraction.

Q. We have heard from several witnesses that there are some specific problems with respect to doing testing on post mortem samples. Would you agree with me that by and large the problem lies not so much in the reading obtained in post mortem samples, as in the interpretation of that reading?

A. Samples of serum, or samples of tissue?

Q. Well, let's take each case. Let us talk first of all about samples of serum, post mortem serum. Would you agree with me that basically the problems indicate, or lead to a result whereby it makes the interpretation somewhat difficult but not necessarily the getting of a reading, the obtaining of a reading?

A. In terms of plasma the getting of a reading would be as easy with an ante mortem sample and a post mortem sample. On the other hand, an ante mortem sample taken from let's say the arm or the leg, the blood would be circulating and the



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2 results would possibly be comparable.

3 If on the other hand, the patient
4 dies and the blood sample was taken at some time
5 after that, and depending where that sample was
6 taken from. If it was taken from say the heart,
7 or the part of the brain, or the leg, or the arm,
8 there could be quite different readings in those
9 different locations.

10 Q. And we have heard evidence
11 to that effect. What I am saying and I am asking you
12 to either agree or disagree with me is would you not
13 agree that the basic problem with post mortem
14 samples is one of interpretation rather than the
15 actual obtaining of a reading? In other words, you
16 can find out the information, you can get the
17 level, the significance of that the interpretation
18 that you put on it is another matter.

19 A. Yes, perhaps the interpretation
20 is a more difficult aspect.

21 Q. And would that also apply,
22 would that logic also apply to testing done on post
23 mortem tissue?

24 A. It would be even more so I
25 think a problem there.

Q. Now, as I understand your



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2 primary function during the period we have been
3 talking about July 1980 to March 1981, it was the
4 monitoring of digoxin levels on patients who were
5 known to be receiving therapeutic dosages of the
6 drug?

7 A. Yes.

8 Q. Now I realize that there has
9 to be some element of interpretation in the
10 performance of your duties. Isn't it fair to say
11 that basically the interpretation of the results
12 that you obtain would have been done by the treating
physician?

13 A. Yes.

14 Q. So if you find a reading that
15 alarmed you, and I don't mean alarm in a pejorative
16 sense, but you found was rather high, or high end
17 of the therapeutic range, you would report that
18 to the physician and it would be his judgment call
as to whether or not to reduce the dosage?

19 A. Yes.

20 Q. So he would basically be doing
21 the interpreting, is that correct?

22 A. Yes.
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Q Now during the period we have been dealing with July 1980 to 1981, were there tests that you were aware of, and I am only referring now to your service, not that of Dr. Soldin, that were done by your Lab on post mortem samples either serum or tissue?

A During the period?

Q July 1980 to March '81?

A Yes, I think I indicated there was one case that I knew of, Pacsai, there was another case prior to that and those were the only two post mortem samples that I knew of.

Q So as far as you know of there were only two done during that period?

A Yes.

Q I take it that in the case of Estrella, this was done at the specific request of the treating doctor?

A At the specific request of the

Q Of the pathologist.

A I believe it was the pathologist,

Q Was there not a testing done on the Estrella baby prior to death as well, was she not being monitored prior to death?



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A. Do you have a comment on that?

MS. CRONK: Thank you for anticipating me, Dr. Ellis. Again, Mr. Commissioner, I hesitate to intervene but once again as all counsel know there will be a wealth of evidence from this witness and others as to specific tests that were done, including the tests that may or may not have been done on babies Estrella, Pacsai and the one other that Dr. Ellis mentioned which I added up to three, Mr. Tobias, but perhaps I misinterpreted that. So I rise at this time because once again I think that question is more appropriately reserved until a later date.

MR. TOBIAS: Mr. Commissioner, my only concern is, my original question was at whose request the test was done. I want to make it very clear I am not referring now to, if there was testing, we haven't had the question answered, but if there was testing done ante mortem, I am not referring to that testing in terms of who made the request, I am referring now to the one instance that Dr. Ellis has referred me to where there was post mortem testing done on Estrella. The only thing I am interested in finding out is whether that test was done at the specific requisition of the treating doctor or the pathologist, that particular test, the post mortem test?



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THE COMMISSIONER: Isn't that what -
Paragraph 103, the Statement of Facts. I don't know,
do you know anything about that test?

THE WITNESS: I don't remember the
exact signature that was on the requisition of the
person requesting that test. My recollection is that
it was the pathologist that was asking that particular
test.

MS. CRONK: Well again, sir, and in
fairness to this witness because of the ambit of the
evidence that it was intended to give, no request
was certainly made by Commission Counsel that he
review those test results of the tests that were
undertaken.

THE COMMISSIONER: It will certainly
come up, Mr. Tobias.

MR. TOBIAS: I am satisfied that
other witnesses will be called.

THE COMMISSIONER: He will also
probably deal with it when he comes back.

MR. TOBIAS: Q. With respect to the
instance that you are aware of, or let me say the
instances that you are aware of where your Laboratory
was involved in testing post mortem samples, is it
fair to say that that particular kind of request



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during that time period was not a routine request?

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A. That is fair to say, yes.

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Q. I mean there were only three

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in a period of six months and I take it that was not

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the standard normal procedure at that time?

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A. There were the Pacsai and Allana Miller. There were a number after that time but, in the run up to this period, there were only, as I say, I think a couple of patients.

Q. Now finally, are you familiar, or were you familiar with the procedures for autopsies at the Hospital between July 1980 and March 1981?

A. No.

Q. Are you familiar today with what the procedures were then?

A. What do you mean by "procedures"?

Q. Okay. Let me be specific.

Was it the routine or standard practice, or, to define it even further, the practice, let us say, in the majority of cases, on autopsy to do testing for toxicology?

A. I do not think it was a routine procedure, no. I do not think there was any indication to do that in the majority of cases.

Q. If the autopsy in question had failed to establish to the satisfaction of the pathologist the cause of death, was it then routine to do toxicology testing as a part of the autopsy?

A. I don't think it was then



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routine, no. I think, when a number of abnormalities have been discovered at autopsy, then --

Q. I'm sorry, I missed part of that response, when the door was closing. Could you repeat the last few words.

A. I think the responsibility for determining the cause of death lies with the pathologist and the physician and, if they discover a certain number of anomalies or abnormalities in the patient that they feel can account for the child's death, then I think they are satisfied that they have come across the cause of death.

Q. The other thing I am interested in knowing is, during the timeframe that we are talking about, July 1980 to March 1981, if, as a result of an autopsy, the pathologist had requested toxicology tests, who would perform those tests?

A. What do you mean by "toxicology"? Do you mean digoxin or potassium or do you mean valium, or what kind of test do you mean?

Q. Specifically, with respect to digoxin, if a request had been made for detection of digoxin as the result of an autopsy, would that have been done by your service?

A. I think it probably would, yes.



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Q. And you are only aware of the three instances in the timeframe that we are talking about?

A. I think so, yes. These would just come in as a blood sample and a requisition, and they may not even be identified as an autopsy, of necessity.

Q. Forgive my ignorance as a layperson but, with respect to testing for other drugs, was there any routine or standard requisition? In other words, if an autopsy failed to establish to the satisfaction of the pathologist the cause of death and he wanted a general run of tests done for toxicology, was there a standard requisition to test for certain drugs?

A. I don't think there was a standard requisition to test for certain drugs specifically.

Q. So, from case to case, it would differ as to what they wanted you to test for?

A. What they wanted to be tested for by myself or other people.

MR. TOBIAS: Thank you, Dr. Ellis.

THE COMMISSIONER: I think we might adjourn until -- You have nothing, Miss Cronk, that



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you want to say?

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We will rise then until ten o'clock

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tomorrow morning.

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MS. CRONK: Thank you, Mr. Commissioner.

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---whereupon the hearing was adjourned at 5:00 p.m.
until Wednesday, the 6th day of July 1983 at
10:00 a.m.

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